

EXHIBIT 39

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:

All Actions MDL No.
15-2666 (JNE/FLM)

VIDEOTAPED DEPOSITION

OF

CHRISTOPHER NACHTSHEIM

Minneapolis, Minnesota

Tuesday, November 29, 2016

Reported by:
Amy L. Larson, RPR
Job No. 113495

1 NACHTSHEIM

2 APPEARANCES:

3 ON BEHALF OF 3M:

4 CHRISTIN GARCIA, ESQUIRE

FAEGRE BAKER DANIELS

5 2200 Wells Fargo Center

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6 Minneapolis, MN 55402

7 DEBORAH LEWIS, ESQUIRE

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10 FOR THE PLAINTIFF:

12 MICHAEL SACCHET, ESQUIRE

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14 Minneapolis, MN 55402

15
16
17 ALSO PRESENT: Kraig Hildahl, Videographer

NACHTSHEIM

INDEX:

EXAMINATION BY:	PAGE
Ms. Garcia.....	8, 372
Mr. Sacchet.....	254
EXHIBITS MARKED FOR IDENTIFICATION:	
Exhibit 1.....	10
Acknowledgment and Agreement to be Bound	
No Bates	
Exhibit 2.....	10
Notice of Videotaped Deposition of	
Christopher Nachtsheim	
No Bates	
Exhibit 3.....	12
Christopher Nachtsheim, Ph.D.,	
Curriculum Vitae	
No Bates	
Exhibit 4.....	15
Forced-Air warming and ultra-clean	
ventilation do not mix	
No Bates	
Exhibit 5.....	15
Patient Warming Excess Heat:	
The Effects on Orthopedic Operating	
Room Ventilation Performance	
No Bates	
Exhibit 6.....	29
Statistical Analysis for HPS Protocol 003	
Bates Albrecht_0016008 - Albrecht_0016012	
Exhibit 7.....	34
Research Agreement	
Bates Belani_000054 - Belani_000061	
Exhibit 8.....	37
Logistic Regression -	
Mark Albrecht - March 11, 2016	
Bates Albrecht_0002275 - Albrecht_0002278	

NACHTSHEIM

INDEX: (Cont'd.)

EXHIBITS MARKED FOR IDENTIFICATION: PAGE

Exhibit 9.....38

11/1/2013 E-mail Chain

Subject: Re: Analytically speaking

Bates Albrecht_0000101 - Albrecht_0000102

Exhibit 10.....53

3/24/10 E-mail Chain

Subject: First Publication I'd Like to

Include you on

Bates Nachtsheim_0000364 - Nachtsheim_0000382

Exhibit 11.....58

April 2010 E-mail Chain

Subject: Testing

Bates Nachtsheim_0001408 - Nachtsheim_0001410

Exhibit 12.....62

4/8/10 E-mail

Subject: Update on testing

Bates Nachtsheim_0001571

Exhibit 13.....78

4/9/10 E-mail

Subject: Problem with laminar flow lab

Bates Nachtsheim_0000832 - Nachtsheim_0000833

Exhibit 14.....84

April 2010 E-mail Chain

Subject: Update

Bates Nachtsheim_0001545 - Nachtsheim_0001547

Exhibit 15.....95

May 2010 E-mail Chain

Subject: Abstract "crud and bug"

!!Important!!

Bates Nachtsheim_0000118 - Nachtsheim_0000120

Exhibit 16.....100

5/29/10 E-mail

Subject: Both abstracts,

Statistical files and data files

Bates Nachtsheim_0000191 - Nachtsheim_0000192,

Nachtsheim_0000211 - Nachtsheim_0000223

NACHTSHEIM

INDEX:

EXHIBITS MARKED FOR IDENTIFICATION: PAGE

Exhibit 17.....114

July 2010 E-mail Chain

Subject: Manuscript drafts for meeting

Bates Nachtsheim_0000548 - Nachtsheim_0000549,

Nachtsheim_0000556 - Nachtsheim_0000576,

Nachtsheim_0000600 - Nachtsheim_0000608,

Nachtsheim_0000577 - Nachtsheim_0000599,

Nachtsheim_0000613 - Nachtsheim_0000615

Exhibit 18.....146

7/8/10 E-mail

Subject: Arizant FDA Warning Ltr

Bates Nachtsheim_00000385

Exhibit 19.....188

1/4/11 E-mail Chain

Subject: Article I was talking about

Bates Nachtsheim_0000177 - Nachtsheim_0000179

Exhibit 20.....192

December 2010/January 2011 E-mail Chain

Subject: Rough Copy

Bates Nachtsheim_0001110 - Nachtsheim_0001115,

Nachtsheim_000127 - Nachtsheim_000130,

Nachtsheim_0001199 - Nachtsheim_0001201,

Nachtsheim_0001206

Exhibit 21.....195

Forced Air Warming versus Conductive

Fabric Warming - An Evaluation of

Laminar Operating Room Ventilation Disruption

Bates Nachtsheim_0001206 - Nachtsheim_0001229

Exhibit 22.....205

Implementing Effective SSI Surveillance

No Bates

Exhibit 23.....226

1/25/11 E-mail Chain

Subject: Minor Changes and a Query

Bates Nachtsheim_0000750 - Nachtsheim_0000751,

Nachtsheim_0000727 - Nachtsheim_0000749

NACHTSHEIM

INDEX: (Cont'd.)

EXHIBITS MARKED FOR IDENTIFICATION: PAGE

Exhibit 24.....231

January 2011 E-mail Chain

Subject: Papers you are involved in
Bates Nachtsheim_0000819 - Nachtsheim_0000821

Exhibit 25.....277

April 2015 E-mail Chain

Subject: Statistical Practitioners Forum:
Advanced DOE Class
Bates 3MBH01293497 - 3MBH01293499

Exhibit 26.....322

Doctor Says a Device He Invented
Poses Risks

No Bates

Exhibit 27.....333
Table

Bates Albrecht_0002298

Exhibit 28.....341

Would Complications Following Rivaroxaban
Administration - A Multi-Centre Comparison
with Low Molecular Weight Heparin for
Thromboprophylaxis in Lower Limb
Arthroplasty

Bates Nachtsheim_0000451 - Nachtsheim_0000466

Exhibit 29.....369

Forced-Air Warming Does Not Worsen Air
Quality in Laminar Flow Operating Rooms
Bates 3MBH00985628 - 3MBH00985633

Exhibit 30.....377

Curriculum Vitae

1 NACHTSHEIM

2 THE VIDEOTAPED DEPOSITION OF CHRISTOPHER
3 NACHTSHEIM, taken on this 29th day of November,
4 2016, at the Law Offices of Faegre Baker
5 Daniels, LLP, 2200 Wells Fargo Center, 90 South
6 Seventh Street, Minneapolis, Minnesota, commencing
7 at approximately 9:11 a.m.

8
9 P R O C E E D I N G S

10
11 THE VIDEOGRAPHER: This is the
12 Start of tape labeled number 1 of the
13 videotaped deposition of Christopher
14 Nachtsheim in the matter of In Re: Bair
15 Hugger Forced Air Warming Products Liability
16 Litigation in the U.S. District Court for the
17 District of Minnesota, Case Number 15-2666
18 (JNE/FLM).

19 This deposition is being held at the
20 Faegre Baker law firm in Minneapolis,
21 Minnesota, on November 29th, 2016. We are
22 going on the record at 9:11 a.m. My name is
23 Kraig Hildahl, I'm the legal video specialist
24 from TSG Reporting. The court reporter is
25 Amy Larson also in association with

1 NACHTSHEIM

2 TSG Reporting.

3 Will counsel please introduce
4 themselves for the record.

5 MS. GARCIA: Christin Garcia,
6 counsel for defendants 3M and Arizant.

7 MS. LEWIS: Deborah Lewis also
8 counsel for defendants 3M and Arizant.

9 MR. SACCHET: Michael Sacchet for
10 plaintiffs.

11 THE VIDEOGRAPHER: Will the court
12 reporter please swear in the witness and then
13 we can proceed.

14
15 CHRISTOPHER NACHTSHEIM,
16 a witness in the above-entitled action,
17 after having been first duly sworn, was
18 deposed and says as follows:

19
20 EXAMINATION

21 BY MS. GARCIA:

22 Q. Hello, Professor Nachtsheim.

23 A. Hello.

24 Q. Thank you for coming here today. Could you
25 start by, for the record, just providing your

1 NACHTSHEIM

2 full name and spell your last name and let us
3 know your address.

4 A. Christopher John Nachtsheim. And it's N as
5 in north, A-C-H-T, S as in Sam, H-E-I-M.
6 Address is 1789 Summit Avenue, St. Paul,
7 Minnesota 55105.

8 Q. Thank you. Have you ever been deposed
9 before?

10 A. Yes.

11 Q. Okay. The one rule of deposition I just want
12 to reinforce today is if you have any
13 difficulty understanding -- well, if you
14 don't understand my question, if you would
15 like me to clarify something, will you please
16 let me know that?

17 A. Uh-huh. Yes.

18 Q. Yes?

19 A. Yes.

20 Q. There's rule number 2.

21 A. That's rule number 2, I knew that.

22 Q. You will need to say things out loud so that
23 we can get an accurate transcription of the
24 record in writing where your head movements
25 can't be taken down, and then we will try not

1 NACHTSHEIM

2 to speak over each other so that we can get a
3 clear record.

4 If at any time you need a break for
5 any reason, please let me know.

6 A. Yes.

7 (Whereupon, Exhibit 1 was
8 marked for identification.)

9 BY MS. GARCIA:

10 Q. I would -- we have marked as Exhibit 1 your
11 signature on the Attachment A to the
12 protective order, is that correct that you
13 filled this out here this morning and signed
14 this?

15 A. I did, yes.

16 Q. And you had the opportunity to review that
17 before today?

18 A. Yes.

19 Q. I would like to also mark as Exhibit 2 the
20 notice of this deposition. This is the
21 original notice for the original day and
22 attached to it is our request for you to
23 provide certain documents.

24 (Whereupon, Exhibit 2 was
25 marked for identification.)

1 NACHTSHEIM

2 BY MS. GARCIA:

3 Q. Did you receive a notice for your deposition
4 here?

5 A. I -- yes, I did.

6 Q. And did you receive Exhibit A with the
7 request for documents?

8 A. Yes, I did.

9 Q. You did produce documents?

10 A. Yes, I did.

11 Q. Did you review all of the requests 1 through
12 39 and make an effort to locate items that
13 are responsive to those requests?

14 A. Yes, I did.

15 Q. And did you provide those to us?

16 A. Yes, I did. Could I just double-check on
17 something?

18 Q. Sure.

19 A. (Reviews document.) I was just looking for
20 my notes on this. But, anyway, it's okay.

21 Q. You're sure?

22 A. Yeah.

23 Q. Okay. Is there any category for which you
24 believe you have documents that would respond
25 to the category that you've not provided?

1 NACHTSHEIM

2 A. Not that I know of.

3 Q. I'm not going to go through the documents at
4 this time. I may come back to certain
5 requests after we talk through some things,
6 because I do have the documents that you
7 provided.

8 So I'm going to mark as Exhibit 3 a
9 copy of your curriculum vitae and --

10 MR. SACCHET: Do you needs copies?

11 MS. GARCIA: Well, I don't think I
12 have copies. If you have one -- I'm okay
13 without -- I brought copies, but I'm not
14 locating them, so I'm okay to just provide
15 the witness with this copy.

16 MR. SACCHET: It might be helpful
17 for me just to know that it's the same copy
18 that at least I'm working off of.

19 MS. GARCIA: (Hands document.)

20 (Whereupon, Exhibit 3 was
21 marked for identification.)

22 MS. GARCIA: Oh, I have them.

23 MR. SACCHET: (Reviews document.)

24 Okay. Yeah, it's the same.

25 MS. GARCIA: Here you go.

1 NACHTSHEIM

2 (Hands document.)

3 BY MS. GARCIA:

4 Q. Exhibit 3 is a copy of your curriculum vitae
5 that I obtained on the Internet, and I
6 understand you may have provided your CV to
7 someone electronically in response to the
8 subpoena, but I did not see it. I do not
9 recall having seen it. So I would ask if you
10 take a look at Exhibit 3 and see if it
11 appears to be up to date. I do believe 2011
12 was the date --

13 A. Yeah, this is -- it's not up to date at all.

14 Q. It's not up to date at all. Okay. Do you
15 believe that you did provide an up-to-date
16 CV?

17 A. Well, I believe I did. In fact, I looked
18 yesterday and I noticed that I had updated it
19 on August 28th or something like that and --
20 but I didn't -- I didn't check the e-mail to
21 see if I had sent it. I think I did.

22 Q. We will check on that.

23 MS. GARCIA: I wonder if you might
24 e-mail to Mary, Deborah, and see if she has
25 it and if she e-mails it to Jeff Woshiowski

1 NACHTSHEIM

2 (phonetic) then we could print it out and
3 have it come down.

4 BY MS. GARCIA:

5 Q. But could you let me know now while we're on
6 the subject if there are any additional
7 papers that would appear on your updated CV
8 that relate to patient-warming devices?

9 A. If this -- does this have the two -- well,
10 let me check.

11 Q. McGovern and Belani? It does have McGovern
12 and Belani.

13 A. Yeah, McGovern, Albrecht, Belani, and then
14 the other one was Belani, Albrecht, McGovern.

15 Q. Why don't you check on the --

16 A. I'll check.

17 Q. -- to confirm that it is what you think. If
18 you look at item number 54 on page 5 --

19 A. Uh-huh.

20 Q. -- why don't you check that against the
21 article you were looking at --

22 A. Sure.

23 Q. -- to make sure that's the same thing.

24 A. (Reviews document.)

25 Q. And item number 58.

1 NACHTSHEIM

2 A. Fifty-four and 58. (Reviews document.)
3 Yeah, although I think the title has changed.
4 So 54 looks the same as -- that's the one,
5 Do not mix, right, and -- and I believe that
6 58 is the other one, although the -- I guess
7 the title changed along the way. It doesn't
8 match, does it? Excess heat -- no, they
9 changed the title a little bit on it and I
10 have this -- it's incorrect in this.

11 Q. Okay. But you believe --

12 A. But I believe that's the paper.

13 Q. Why don't we mark the two papers so that we
14 can just be clear on the record.

15 A. Okay.

16 (Whereupon, Exhibit 4 and
17 Exhibit 5 was marked for
18 identification.)

19 BY MS. GARCIA:

20 Q. Is Exhibit 4 which study?

21 A. Exhibit 4 is the, Forced Air Warming and
22 Ultra Clean Ventilation Do Not Mix.

23 Q. And Exhibit 5 is Belani --

24 A. Patient warm -- patient warm -- yeah, Belani,
25 Albrecht, et al.

1 NACHTSHEIM

2 Q. As the first author. Okay.

3 So do you believe that Exhibit 4
4 corresponds to item number 54 on your CV
5 which we have marked as Exhibit 3?

6 A. I do.

7 Q. And do you believe that -- thank you --
8 Exhibit 5 corresponds to item 58 we have
9 marked on your -- that's on your CV?

10 A. I do.

11 Q. And I notice that item 60 lists a research
12 article in process. Do you believe that
13 article was ever published?

14 A. I do not.

15 Q. Are there any other research articles that
16 have been published for which you're an
17 author that relate to patient-warming
18 products?

19 A. No.

20 Q. And are there any articles in process that
21 you are seeking publication for on which you
22 are an author?

23 A. No.

24 Q. That relate to patient-warming products.

25 A. Right. No. Yeah, I --

1 NACHTSHEIM

2 Q. Thank you. I just wanted to complete that.

3 A. Yeah.

4 Q. We -- we understood each other, but the
5 record only records it if it happens.

6 A. Okay.

7 Q. Thank you very much.

8 Any other work of any kind related
9 to patient-warming devices that appears on
10 your updated CV?

11 A. No.

12 Q. Thank you.

13 Is Exhibit 3 a complete statement of
14 your professional work and publication
15 through approximately late 2011?

16 A. Yes.

17 Q. Before receiving your notice for deposition
18 in this lawsuit, were you aware of any
19 lawsuits related to the Bair Hugger
20 patient-warming system?

21 A. No.

22 Q. Have you and I ever spoken before I walked in
23 the room this morning?

24 A. No.

25 Q. Have you ever spoken with any other lawyers

1 NACHTSHEIM

2 representing 3M or Arizant for purposes other
3 than logistics of arranging the deposition?

4 A. No.

5 Q. Have you ever had any kind of communication
6 with me at all other than today?

7 A. No.

8 Q. And have you ever had any communication with
9 lawyers for 3M or Arizant in the Bair Hugger
10 litigation other than arranging for your
11 deposition and production?

12 A. No.

13 Q. Thank you.

14 Have you ever spoken with anyone who
15 you understand to be a lawyer for the
16 plaintiffs in this litigation?

17 A. No, although I've done work with the Ciresi
18 law firm.

19 Q. Okay. Can you tell me about that, please.

20 A. Well, this must have been, I don't know, five
21 or six years ago, maybe even seven, and there
22 was a -- it was a lawsuit by Delta dental
23 against some -- some -- a practice, and so I
24 was brought on as an expert to look at the
25 data and kind of give my opinion about

1 NACHTSHEIM

2 whether or not there was systematic
3 overcharging going on and -- and so I served
4 in that capacity.

5 Q. Which party did the Ciresi law firm
6 represent?

7 A. Delta Dental.

8 Q. Have you spoken with anyone from the Ciresi
9 law firm about the Bair Hugger litigation?

10 A. No.

11 Q. Have you spoken with anyone who you
12 understand to be -- well, have you
13 communicated in writing with anyone who is a
14 lawyer for the plaintiffs, including the
15 Ciresi law firm, about the Bair Hugger
16 litigation?

17 A. No.

18 Q. Have you communicated with anyone who you
19 understand to be an expert for the plaintiffs
20 in the Bair Hugger litigation?

21 A. No.

22 Q. Did you speak with anyone about the fact that
23 you were going to have a deposition?

24 A. My wife.

25 Q. Anyone else?

1 NACHTSHEIM

2 A. Maybe a couple of friends, I don't know,
3 just -- just -- yes, I did -- wait. I
4 just -- a friend of mine is a lawyer and I
5 called when I -- and I asked --

6 Q. Well, if you were seeking legal advice, you
7 shouldn't tell me about it.

8 A. Okay.

9 Q. So that's -- that's fine.

10 A. I'm okay.

11 Q. Other than something -- other than speaking
12 with a lawyer about counseling or advice that
13 you might take into the deposition, anyone
14 else that you spoke with?

15 A. No.

16 Q. Did you do anything to prepare for your
17 deposition?

18 A. The only thing I've done is review the --
19 review my e-mails that I -- the materials
20 that I submitted and review the papers.

21 Q. Okay. Thank you.

22 Do you know Dr. Scott Augustine?

23 A. Yes.

24 Q. How?

25 A. Well, I worked -- when I began working with

1 NACHTSHEIM

2 Mark Albrecht and we began working on the
3 forced-air warming sort of project, I met him
4 once at his house.

5 Q. Only once ever you've met him?

6 A. Only once ever.

7 Q. Okay. Was that a social occasion or did you
8 also --

9 A. Yes.

10 Q. It was?

11 A. It was a social occasion.

12 Q. Did you happen to speak about the patient
13 warming work while you were there?

14 A. You know, I don't remember. You mean to him?

15 Q. Yes.

16 A. I don't remember that we did. I didn't get
17 much time with him. It was a big group.

18 Q. Have you --

19 A. I might have. I don't know.

20 Q. Okay. That's fine.

21 Have you ever spoken with him before
22 on the telephone?

23 A. Not that I recall.

24 Q. And other than I have seen some e-mails
25 produced by you or produced by Mr. Albrecht

1 NACHTSHEIM

2 that have Scott Augustine as a copy on the
3 e-mail, other than those type of e-mail
4 communications that involved Mark Albrecht
5 and you and perhaps Dr. Augustine, have you
6 had written communications with him?

7 A. The only thing -- I don't -- I don't
8 remember. There might -- there might have
9 been a communication with him directly,
10 although, you know, I'm not sure about this.
11 There -- there was a time when Mark was
12 looking at getting his doctorate at the
13 Carlson School and -- and he -- he applied
14 and was accepted and there was a -- sort of
15 a -- there was a -- he had an arrangement
16 with Dr. Augustine to cut his hours back a
17 bit, to keep working but cut his hours back
18 so that he could, you know, pursue his
19 doctorate.

20 And I do recall meeting -- I do
21 recall -- I do recall meeting him to
22 discuss -- Mark was present, to -- to talk
23 about that arrangement and how that all --
24 how that would all work.

25 Q. I believe by "him" you mean Dr. Augustine --

1 NACHTSHEIM

2 A. Dr. Augustine.

3 Q. -- is that correct?

4 A. Yeah. I believe the three of us met and --
5 to -- to discuss that arrangement and how
6 that was going to work.

7 Q. Why were you part of that arrangement?

8 A. Well, I was going -- at the time I was
9 department chair to the department that Mark
10 was applying, first of all. And, secondly, I
11 was going to be his thesis advisor.

12 Q. What was the department?

13 A. At that time it was operations and management
14 science at the University of Minnesota in the
15 Carlson School of Management.

16 Q. Did he complete his thesis or earn a Ph.D.?

17 A. No, he -- he began the semester and decided,
18 to my great disappointment, that he -- he
19 really didn't want to get a Ph.D., that he
20 was more interested in -- he was more
21 interested in business.

22 Q. How did you know Mark Albrecht?

23 A. Okay. Mark got his MBA at the University of
24 Minnesota. And I didn't have him in class
25 originally. My colleague William Lee had him

1 NACHTSHEIM

2 in a -- in a -- actually, a doctoral level
3 statistics class.

4 And Mark was interested in doing
5 research, and so my colleague, William Lee,
6 came to me and said, "I've got this great
7 student who would like to do research in
8 discrete choice experiments, why don't we
9 form a little research group and we'll start
10 working together," and that's what we did and
11 that's how I met Mark.

12 Q. Did you work with Mark on -- I see that
13 you've published with Mark.

14 A. Right.

15 Q. Separate from the patient warming lawsuits --
16 or, I'm sorry, let me start that question
17 over.

18 Separate from papers that address
19 specifically patient-warming devices, it
20 appears from your CV that you have published
21 articles with Mark Albrecht?

22 A. Absolutely.

23 Q. If we would refer for a moment to Exhibit 4,
24 which is the paper with McGovern as the lead
25 author. And I may at many points today refer

1 NACHTSHEIM

2 to this as the McGovern article.

3 A. Okay.

4 Q. Do you know any of the other people who are
5 listed as a coauthor besides Mark Albrecht?

6 A. You know, I don't. I remember the -- the
7 social engagement at Dr. Augustine's that I
8 mentioned, I think one or two of these were
9 there and I think I might have met them
10 there, but I wouldn't be able to identify
11 them now.

12 Q. Do you recall when the social gathering at
13 Dr. Augustine's house was?

14 A. You know, it -- I do not recall the year, but
15 I think it was when these papers were in
16 progress.

17 Q. Meaning they had been submitted to journals?

18 A. They may have been or we -- it was around the
19 time we submitted one of them, anyway, I
20 think it was around that time.

21 Q. And if you would look at exhibit --

22 A. It might have been before, we may have still
23 gathering data, you know, we may have still
24 been writing the papers. I can't -- I'm not
25 absolutely certain.

1 NACHTSHEIM

2 Q. Was there ever any time that you met in
3 person with any of the coauthors on either
4 Exhibit 4 or 5 to discuss the substance of
5 the papers or the work that underlied the
6 papers?

7 A. Not outside of Mark Albrecht.

8 Q. So then turning to Exhibit 5, which has
9 Belani has the first author, and I may refer
10 to this as the Belani paper --

11 A. Okay.

12 Q. -- at certain points. Well, I was going to
13 ask you if you know any of those coauthors,
14 but they're the same people, so --

15 A. Yeah.

16 Q. -- I take it the answer is the same?

17 A. Better be, yeah.

18 Q. Dr. Belani is, I believe, affiliated with the
19 University of Minnesota, but you've not known
20 him?

21 A. That's right, I've not known him.

22 Q. Outside of perhaps speaking with one of these
23 gentleman at Dr. Augustine's house at the
24 gathering you've mentioned, have you ever
25 spoken by phone with any of the coauthors

1 NACHTSHEIM

2 on either Exhibit 4 or 5 other than
3 Mark Albrecht?

4 A. Not to my knowledge. I don't remember ever
5 having done that.

6 Q. In terms of the contributions that you made
7 or the investigations that you undertook
8 related to the work that formed the basis for
9 these two papers, Exhibits 4 and 5, is all
10 of that work either occurring in meetings
11 with Mark Albrecht or phone calls with
12 Mark Albrecht or reflected in the e-mails
13 that you produced in the attachments to those
14 e-mails?

15 A. That's the way I see it. It was all with
16 Mark, and it's probably laid out in those
17 e-mails.

18 Q. Before beginning work -- actually, I'm going
19 to hold that question, excuse me.

20 Outside of your work that related to
21 the papers identified as items 54, 58 and 60
22 on your CV or that may be reflected in the
23 e-mails you've produced in this case, have
24 you ever done any other work for Dr. Scott
25 Augustine or any of his companies, including

1 NACHTSHEIM

2 Augustine Biomedical?

3 A. Yes.

4 Q. Can you tell me about that, please.

5 A. So there was work on -- there was work on a
6 product called -- oh, heck, Pure -- Pure
7 Zone, Pure Air, something like that. It
8 was -- it was a product that -- so -- so the
9 idea of the product was for people with
10 allergies who have difficulty sleeping to be
11 able to put this -- this -- essentially, a
12 pillow case over their pillow and then pure
13 air was piped into that pillow case and
14 filtered up so that the patient is breathing
15 pure -- pure air all night long.

16 Q. Okay. I think I may have a protocol from
17 that study, and I was going to ask you about
18 that.

19 Well, first of all, before I get
20 that out, was that the only other work you've
21 done for Dr. Augustine or one of his
22 companies?

23 A. Yes.

24 Q. Okay. Did that result in a publication?

25 A. I believe it did. And it would have --

1 NACHTSHEIM

2 should have -- should have predated these.

3 MR. SACCHET: If you don't mind me
4 interjecting, I'm getting texts that the
5 video is frozen or extremely buggy. I don't
6 know if there are ways to remediate that
7 before, you know, going forward. It's not an
8 issue on our part, but I just thought I'd
9 note it for the record.

10 MS. GARCIA: Thank you. I assume
11 Kraig will look into -- or keep going? Okay.

12 THE WITNESS: Number 49 on -- on
13 this CV -- CV.

14 BY MS. GARCIA:

15 Q. Is the published article related to that
16 work?

17 A. Uh-huh. Yes.

18 Q. What was your role in that work?

19 A. To help design the study and analyze the
20 data.

21 (Whereupon, Exhibit 6 was
22 marked for identification.)

23 BY MS. GARCIA:

24 Q. This is not a complete document, Exhibit 6.

25 It was a long document, and since it doesn't

1 NACHTSHEIM

2 relate directly to patient warming, I just
3 copied off the first few pages. This is
4 produced by Mark Albrecht, as indicated by
5 the Bates number on the bottom. And I just
6 wanted to ask if this is the protocol for the
7 study you were just referencing. Or at least
8 it's -- the document is titled, "Statistic
9 Analysis for HPS Protocol 003." Does this
10 relate to the study we were --

11 A. Yes, it does.

12 Q. Is this type of document, a statistical
13 analysis detail provided in this type of
14 document -- let me take that question back
15 and ask you a different question.

16 Was this document created before or
17 after the statistical analysis was done for
18 the study?

19 A. You know, I don't know. I'm not -- I'm not
20 actually familiar with this. I'm familiar
21 with the study and I recognize -- I recognize
22 the design, but I don't -- I don't recall --
23 well, wait. It's been a while. So your
24 question was?

25 Q. Let me back up and ask a different question

1 NACHTSHEIM

2 first, which is do you recall seeing this
3 document?

4 A. Well, I -- I actually don't recall, but my
5 name is on it, so I probably did.

6 Q. Well, your name is on it as an author of the
7 study, correct?

8 A. Okay. Right.

9 Q. Is that right?

10 A. Yes.

11 Q. Is that what you're referring, to the authors
12 line on the first page?

13 A. Yeah, the authors line on the first page.

14 Q. Okay. Do you believe this is the type of
15 document that would be created before the
16 study was conducted or after the study was
17 conducted?

18 MR. SACCHET: Object to form,
19 calls for speculation.

20 BY MS. GARCIA:

21 Q. Do you have any understanding about that one
22 way or the other?

23 A. I don't. I really would have to study this
24 document that --

25 Q. Well, and I have not even copied the whole

1 NACHTSHEIM

2 document so --

3 A. Okay.

4 Q. -- I just wanted to use this as a grounding
5 to -- by comparison. I did not see anything
6 like this for either Exhibit 4 or Exhibit 5
7 or item 60 on your CV, any of the
8 patient-warming studies, I did not see
9 anything that looked to me similar to this
10 type of statistical analysis plan or
11 document.

12 A. Okay.

13 Q. Do you believe that anything like that exists
14 for those studies, the patient-warming
15 studies?

16 MR. SACCHET: I'm going to object
17 to form again.

18 THE WITNESS: I -- I don't --
19 yeah, I don't -- I'm not aware of anything
20 like -- like -- you know, like this document
21 existing for those studies, I'm just not
22 aware of it.

23 BY MS. GARCIA:

24 Q. Did you see any written statistical analysis
25 plan for any of the patient-warming studies

1 NACHTSHEIM

2 at any time?

3 A. I don't believe I saw a written plan. There
4 were -- yeah, I don't believe I saw a written
5 plan.

6 Q. Have you seen anything -- you seem to be
7 pausing and so I want to --

8 A. Sure.

9 Q. -- ask for what you are thinking of.

10 A. Well, the -- the analysis of a well-designed
11 study like this is fairly standard and, I
12 mean, there are standard methods for doing --
13 for analyzing a particular clinical trial as
14 this is. And so when -- I do recall that
15 when we got to analyzing the data, Mark
16 shared his initial analyses with me and asked
17 me to go through them and -- and to -- to be
18 sure he was doing things correctly and so
19 forth.

20 Q. Okay. I will -- we have e-mails with
21 attachments for that and we'll take that up
22 when we get to those particular studies.

23 A. Okay.

24 Q. Thank you.

25 MS. GARCIA: I would like to mark

1 NACHTSHEIM

2 as Exhibit 7 this document.

3 (Whereupon, Exhibit 7 was
4 marked for identification.)

5 BY MS. GARCIA:

6 Q. Exhibit 7 is something that was produced by
7 Dr. Belani. It is a research agreement
8 between he and Augustine Biomedical, and
9 there is a protocol attached for a randomized
10 trial.

11 Did you ever have a written research
12 agreement with Augustine Biomedical or any
13 other company related -- or entity or person
14 related to your patient warming work?

15 A. I don't -- I don't recall outside of, of
16 course, when I started working with Augustine
17 on sort of a consulting agreement of some
18 kind. But I don't recall a -- I just don't
19 recall a particular research agreement for,
20 you know, one of the studies.

21 Q. So you did have a consulting agreement with
22 Augustine related to -- to what?

23 A. You know, I don't think I was able to find
24 it, but it was -- it was basically related
25 to -- originally, it was to the Pure Air --

1 NACHTSHEIM

2 the Pure Air work and I think to work with
3 Mark in the statistical studies that he was
4 carrying out.

5 Q. Do you recall anything about the terms of the
6 agreement?

7 A. Very little. I really don't recall a lot. I
8 think it was an hourly basis for my work.

9 Q. Do you recall what you were being paid an
10 hour?

11 A. I don't.

12 Q. Can you ballpark it for me?

13 MR. SACCHET: Calls for
14 speculation.

15 THE WITNESS: It does. Two
16 hundred and fifty, \$300 an hour, something
17 like that.

18 BY MS. GARCIA:

19 Q. Do you feel confident that it was less than
20 \$500 an hour?

21 A. Oh, yes.

22 Q. Do you feel confident that it was more than
23 \$150 an hour?

24 A. Yes.

25 Q. Do you believe you were -- do you recall that

1 NACHTSHEIM

2 you were paid for your work on the
3 patient-warming studies on an hourly basis?

4 A. Yes.

5 Q. Is there -- do you recall the total amount of
6 money, can you ballpark for me in any way the
7 total amount of money that you earned for
8 working on any project that was for
9 Augustine?

10 A. That's a really good question. On any --
11 were you asking about any particular -- there
12 was the two -- sort of two --

13 Q. Total together or separate, however you
14 recall it.

15 A. I really -- I really can't. I mean, I'm --
16 I'm quite confident it was less than \$20,000,
17 probably more than a few thousand dollars,
18 but I just -- I don't remember the exact
19 amounts.

20 Q. Have you ever had any type of ownership
21 interest in any Augustine company?

22 A. No.

23 Q. Have you ever had any type of ownership
24 interest for any patient-warming product?

25 A. No.

1 NACHTSHEIM

2 Q. Did you ever see any protocol -- to your
3 knowledge, did you ever see this protocol, to
4 your knowledge, that's within Exhibit 7?

5 A. I never saw this, to my knowledge.

6 (Whereupon, Exhibit 8 was
7 marked for identification.)

8 BY MS. GARCIA:

9 Q. Exhibit 8 is a recent document produced by --
10 recent in date produced by Mark Albrecht, and
11 I just wanted to see if you know anything
12 about what this is referring to?

13 A. (Reviews document.) I'm not familiar with
14 this.

15 Q. Do you believe that this applies to -- are
16 you able to make a judgment by look -- well,
17 okay. Let me -- let me set a better
18 foundation than that.

19 This is titled, "Logistic
20 Regression," and there's a series of, I take
21 it, statistical analysis results attached; is
22 that right?

23 A. Yes.

24 Q. By looking at this document, are you able to
25 tell me one way or another whether this

1 NACHTSHEIM

2 statistical analysis applies to either
3 Exhibit 4 or Exhibit 5?

4 MR. SACCHET: Object to form.

5 THE WITNESS: I'm not aware of any
6 way that this is connected to those two
7 papers. This -- this looks to me like a
8 different analysis.

9 BY MS. GARCIA:

10 Q. And I am -- based on your statistical
11 expertise, are you able to make a good
12 estimation of that by looking at the type of
13 information that's available on Exhibit 8?

14 A. Yes.

15 MR. SACCHET: Objection;
16 foundation.

17 BY MS. GARCIA:

18 Q. You may be noticing I have a series of just
19 miscellaneous documents I'm beginning with
20 before we get into the meat of your work, and
21 here is another one, Exhibit 9.

22 (Whereupon, Exhibit 9 was
23 marked for identification.)

24 BY MS. GARCIA:

25 Q. This is a November 1st, 2013, e-mail produced

1 NACHTSHEIM

2 by Mark Albrecht. And in the third paragraph
3 he is talking about, "You guys could have
4 mentioned that you had a bonehead MBA student
5 engineer that was running thermo-regulatory
6 experiments that was sorting the randomizer
7 run order" -- "randomized run order of course
8 in a garage and operating theater made of
9 garbage bags. Maybe mention that this is the
10 norm for the industry or at least what you
11 might expect from a guy that runs experiments
12 in a garage, ha ha."

13 Do you know what he's speaking about
14 there?

15 A. Yes, I do. I think I do. So the -- the
16 original work when -- when he started to work
17 on the forced-air warming problem, they
18 had -- he had built a simulated operating
19 room and ran some experiments with that. And
20 it wasn't a garage, but it was a -- it was a
21 warehouse that they had rented so they could
22 build this simulated operating room, I think
23 that's what this is referring to, and -- and
24 there were some experiments run there and --
25 and -- so, yeah.

1 NACHTSHEIM

2 Q. Okay. First you say they've built and you
3 also said they rented, and I just want to
4 make sure I understand what you're saying.
5 Do you believe there was a preexisting
6 warehouse that they rented and then did some
7 modification to the inside?

8 A. That's my understanding.

9 Q. Okay. Did you have anything to do with that
10 design or construction work?

11 A. Not with the construction work, no.

12 Q. Or the design of the operating room, whatever
13 they did to modify the inside?

14 A. I did -- I did not.

15 Q. Okay. And when you say they built an
16 operating, can you give me a better sense of
17 what you mean, what did they do inside the
18 warehouse?

19 A. Well, as I recall, there was an area closed
20 off and there -- I don't remember the
21 technical term for the fan that brings air
22 down and causes the -- the downward gradient,
23 and so there was -- so as I recall, that was
24 part of the -- part of the sort of simulated
25 operating room.

1 NACHTSHEIM

2 Q. And we will get to an e-mail discussing this
3 later, but I do have an under -- well, let me
4 strike that and start over.

5 Were you ever in this warehouse?

6 A. Yes.

7 Q. Did you observe an experiment being conducted
8 in the warehouse?

9 A. Yes.

10 Q. Do you --

11 A. I observed part of an -- I did not observe an
12 entire experiment, I observed part of an
13 experiment.

14 Q. Did you observe an experiment that involved
15 the operation of a forced-air warming device?

16 A. I believe I did. I think I did.

17 Q. Do you know if it was a Bair Hugger device?

18 A. I think it would have been a Bair Hugger,
19 yes. I'm just not positive whether I was
20 watching -- you know, when I -- I believe
21 that -- I believe that they were doing
22 experiment -- part of the experiment involved
23 the Bair Hugger device and -- and I would
24 guess the -- the HotDog or something like
25 that. So I don't recall with a hundred

1 NACHTSHEIM

2 percent certainty that there was a
3 Bair Hugger when I happened to be there
4 watching.

5 Q. Do you recall anything about how long you
6 were there in the warehouse watching?

7 A. I -- I believe I was just there for a couple
8 of hours.

9 Q. Were you there to provide any type of advice
10 or consultation to them about the way they
11 conducted their study?

12 A. Yes. I think Mark -- Mark wanted me to
13 observe how they were carrying out the study
14 and just to give my opinion about was it --
15 were they doing this correctly and so forth.

16 Q. Do you have any expertise in what they were
17 doing in the warehouse?

18 A. Oh, no.

19 Q. So what is it that you were providing advice
20 about?

21 A. Well, for example, making sure that the runs
22 were being carried out in a random order,
23 that they were properly randomized, that the
24 changeover from one run to the next was done
25 appropriately and so forth.

1 NACHTSHEIM

2 Q. Do you know --

3 A. Oh, and also how the measurements were being
4 taken. I mean, Mark wanted me to see how
5 they were doing measurements from each of the
6 runs.

7 Q. When you say, "How the measurements were
8 being taken," can you tell me more about what
9 you mean?

10 A. Well, this is all vague in terms of the
11 warehouse, but the -- how you go about
12 counting bubbles in certain areas of the
13 room.

14 Q. Did you provide any expertise or advice about
15 the particular method they were using to
16 generate or track or count the bubbles from a
17 mechanical perspective?

18 A. No, no.

19 Q. So what you were providing insight -- or
20 you -- you were reacting to the way they were
21 documenting their counts?

22 A. I think that's -- that's pretty accurate. I
23 think that's accurate. I -- I was there to
24 observe how they were recording things, how
25 they were carrying out the experiment.

1 NACHTSHEIM

2 Q. Do you know if the work that you observed
3 became part of any paper that you were a
4 coauthor on either that became published or
5 was in process?

6 A. You know, I think there was a draft of a
7 paper that I don't believe ever was
8 published. I think -- that's -- that's my
9 answer. I -- I believe there -- I think there
10 was -- I seem to recall there was a draft
11 and -- but it was not published.

12 Q. Was anyone else in the warehouse when you
13 were there other than Mark Albrecht?

14 A. There was -- I don't recall his name, but
15 there was one other person who I believe
16 worked or reported to Mark or also worked for
17 Dr. Augustine kind of helping to run the
18 experiment, the -- the experiment.

19 Q. Was there anything within the warehouse that
20 you identified as having been constructed to
21 resemble or to be an operating theater?

22 A. Was there anything constructed -- I'm sorry,
23 could you ask me again?

24 Q. Within -- do you have a sense for how big the
25 room was that you were in in the warehouse?

1 NACHTSHEIM

2 A. I have a sense for how big it was.

3 Q. Can you give me a ballpark?

4 A. Maybe it was -- this is -- maybe it was
5 15 by 15. I'm not sure. Twenty by 20. I'm
6 not sure.

7 Q. So the size of a large living room?

8 A. Something like that or a dining room.

9 Q. Was there any structure within the room or
10 was it just the four walls of the room?

11 A. I don't recall structure inside. I don't
12 recall that. I just don't recall. There was
13 a -- I believe there was a table, but that's
14 all I recall.

15 Q. So you recall a table. Do you recall any
16 type of draping?

17 MR. SACCHET: Objection; asked and
18 answered.

19 THE WITNESS: Yeah, I don't recall
20 draping. I just don't recall.

21 BY MS. GARCIA:

22 Q. Do you recall anything in the room at all
23 other than a table?

24 A. You know, I recall the -- I recall the device
25 that produced the bubbles. I think I -- I

1 NACHTSHEIM

2 believe I recall a camera. That's about all
3 I recall.

4 Q. Video or still camera?

5 A. I think it was still, but I'm not sure. I
6 think it was still.

7 Q. And you said that you recalled that there was
8 air coming down from the ceiling?

9 A. Yes.

10 Q. Did you provide any insight or expertise
11 about the way that airflow in the room was
12 being produced or managed?

13 A. No.

14 Q. Did you do any research about what the
15 airflow in the room should be to reflect an
16 accurate operating room setting?

17 A. No, I did not.

18 Q. There's a comment in here about, "Operating
19 theater made of garbage bags." Did you see
20 anything like that?

21 A. I don't recall garbage bags. I don't recall
22 that.

23 Q. Do you recall anything that was an operating
24 theater?

25 A. Do I recall anything that was an operating

1 NACHTSHEIM

2 theater?

3 Q. Uh-huh.

4 A. Just as I said, a table. I recall the -- I
5 recall the -- I think I recall the fan up
6 above. I think there may have been a way to
7 pull the air out, and it was -- as it came
8 down, which was I believe another attempt to
9 simulate an operating room, but I don't
10 recall much more than that.

11 Q. And as you said that, you were moving your
12 arm down towards the floor. Is that what you
13 meant, a way for the air to come down at
14 floor level?

15 A. Down at floor level, yes.

16 Q. Thank you.

17 Do you recall anything about the way
18 the bubbles were moving and how that might
19 relate to a comparison of different
20 patient-warming devices based on your
21 personal observation?

22 A. Based on my personal observation. I -- I --
23 I have recollections of the bubbles moving
24 up, I have recollections of them swirling at
25 times, but I have -- it's very vague. What I

1 NACHTSHEIM

2 recall is very vague.

3 Q. When you were there was there any mannequin
4 on the table?

5 A. I don't remember.

6 Q. And do you recall --

7 A. There may have been, but I don't -- I don't
8 really remember that.

9 Q. Okay. And do you recall any person standing
10 by the table during the time when bubbles
11 were generated to simulate being either --

12 A. Yes.

13 Q. -- to simulate being a doctor?

14 A. I do remember that. Yes.

15 Q. Do you know where around the table that
16 person was standing?

17 A. Well, I -- I'm not sure. I think I remember
18 one person standing by the side perhaps
19 being -- you know, simulating the -- the
20 surgeon, but I -- you know, in the -- in the
21 kind of the middle of the table, but I don't
22 have a great recollection.

23 Q. Okay. Are you an industrial hygienist?

24 A. Am I --

25 Q. An industrial hygienist?

1 NACHTSHEIM

2 A. No, I'm not.

3 Q. Do you have any expertise in the proper
4 filtration or ventilation in hospital
5 operating rooms?

6 A. No, I do not.

7 Q. Are you a medical doctor?

8 A. No.

9 Q. Do you have any specialized training in
10 microbiology?

11 A. No.

12 Q. Do you claim any expertise in microbiology?

13 A. I do not.

14 Q. Do you claim any expertise in evaluating the
15 tests for potential contamination of biologic
16 pathogens in an operating room environment?

17 A. Do you mean -- the tests, do you mean the --
18 the -- evaluating assays?

19 Q. Yes.

20 A. No.

21 Q. Something biologic or microbiologic.

22 A. Numeric is another issue, but -- but no.

23 Q. Have you published anything in the peer
24 review literature about the causes of
25 surgical site infections?

1 NACHTSHEIM

2 A. No.

3 Q. Have you published anything in the peer
4 reviewed literature about filtration of
5 either a room or a medical device?

6 A. Outside of the pure air filtration system,
7 no.

8 Q. Thank you.

9 Have you published any articles on
10 medical device design?

11 A. No.

12 Q. Outside of the work that we've discussed here
13 today, have you worked for a medical device
14 company?

15 A. Yes.

16 Q. Is that something you're able to disclose?

17 A. Yes.

18 Q. Who you worked for?

19 A. Yes.

20 Q. Okay.

21 A. Oh, you want to know?

22 Q. Yes, that would be great if you're able to
23 disclose it.

24 A. I've worked for -- I've worked for Medtronic,
25 I've worked for Guidant, Boston Scientific,

1 NACHTSHEIM

2 I've worked for St. Jude Medical.

3 Q. Has your work involved statistical analysis?

4 A. Yes.

5 Q. Has your work been related to the design of
6 medical devices?

7 A. Yes.

8 Q. Have you published any of that work?

9 A. No.

10 Q. Are you an expert in the substantive design
11 of a medical device?

12 A. No.

13 Q. The process by which we would decide, other
14 than statistical analysis, have you played
15 any role in device design?

16 A. No.

17 Q. Have you done any kind of work on any kind of
18 patient-warming device other than what is
19 reflected in the subject matter we're talking
20 about here today, including the documents
21 that you produced?

22 A. No.

23 Q. Have you ever participated in the design of a
24 patient-warming device?

25 A. No.

1 NACHTSHEIM

2 Q. Do you know what regulations apply to the
3 design and manufacturing of patient-warming
4 devices?

5 A. No.

6 Q. Do you know what standards apply to operating
7 room environments?

8 A. No. I should say outside of what I read in
9 these papers that was provided by the -- that
10 was not provided by me.

11 MS. GARCIA: Can you remind me of
12 my question? I'm sorry.

13 (Whereupon, the last question
14 was read by the court reporter.)

15 BY MS. GARCIA:

16 Q. To the extent that Exhibits 4 or 5 reflect
17 any statements about the standards that might
18 apply to operating room environments, do you
19 claim expertise about those things?

20 A. No, I don't.

21 Q. Before your work for Mark Albrecht --
22 before your work with Mark Albrecht and
23 Scott Augustine, did you have any knowledge
24 about patient-warming devices?

25 A. No.

1 NACHTSHEIM

2 (Whereupon, Exhibit 10 was
3 marked for identification.)

4 BY MS. GARCIA:

5 Q. I have marked as Exhibit 10 an e-mail
6 from Mark Albrecht to you copied to
7 Scott Augustine dated March 24th, 2010.

8 A. Uh-huh.

9 Q. This is marked with your Bates number, which
10 means it would have been produced by you.

11 A. Uh-huh. Yes.

12 Q. It says, "Chris, here is a publication we
13 will be submitting in a couple of weeks. I'd
14 be" -- I'm reading an excerpt from this.
15 "I'd be thrilled if you would like to be a
16 part of this. All I need you to do is take a
17 look at the stats and conclusions and provide
18 some overview and guidance. Let me know if
19 you're interested." Have I read the parts
20 I've read correctly?

21 A. Yes.

22 Q. Is this the first time that you began working
23 with Mark Albrecht on a patient warming
24 paper?

25 A. Well, no. I believe -- well, the work that I

1 NACHTSHEIM

2 believe we did on the paper that I don't
3 think ever went anywhere, some of the earlier
4 experimentation, but -- but I think this is
5 probably the first that I became involved in
6 this particular product -- this particular
7 project.

8 Q. Okay. Well, this particular --

9 A. And I don't know how to say project, but I
10 mean just what led to this paper.

11 Q. Well, this particular draft publication that
12 is attached to Exhibit 10 I believe is not
13 one that resulted in publication. If you
14 would take a look at the attachment to
15 Exhibit 10 --

16 MR. SACCHET: Objection; move to
17 strike the preamble.

18 BY MS. GARCIA:

19 Q. Would you please look at the document
20 attached to Exhibit 10 --

21 A. Uh-huh.

22 Q. -- and tell me if you believe that this
23 manuscript became either Exhibit 4 or
24 Exhibit 5?

25 A. (Reviews document.) I agree, I don't -- I

1 NACHTSHEIM

2 don't believe this led -- this became either
3 of these publications.

4 Q. Okay. And by, "These publications," you're
5 referring to Exhibits 4 and 5?

6 A. Exhibits 4 and 5, right.

7 Q. If you would look at the page ending 370,
8 which is the Methods section.

9 A. Oh, I see the numbers, okay.

10 Q. I will refer often today to the Bates numbers
11 and so I'll just be using the last numbers --

12 A. Right.

13 Q. -- to make it shorter for us.

14 A. Got it. Okay, 370 I'm there.

15 Q. The Methods section. Do you believe that
16 this describes the same setting that you were
17 describing a moment ago when you went to the
18 warehouse and observed the experiment that
19 you described?

20 A. (Reviews document.) This very well could
21 have been related to the experiment in the
22 simulated operating room.

23 Q. Are you able to tell for sure one way or the
24 other?

25 A. I -- I can't tell for sure one way or the

1 NACHTSHEIM

2 other. Do they -- I can't tell for sure.

3 Q. Do you -- have you ever been to any other --
4 have you ever been to any -- this describes a
5 laminar flow laboratory on page 370. Have
6 you ever been to anything other than the
7 warehouse that you just described?

8 A. No.

9 Q. Are you aware of any other type of structure
10 in which Mark Albrecht has done any bubble
11 testing other than when you visited?

12 A. No, outside of --

13 Q. And at -- at hospitals.

14 A. Outside of hospitals, no.

15 Q. Okay. I do believe this is the earliest work
16 referenced in the e-mails you provided. Do
17 you believe there is something earlier -- let
18 me ask this a different way.

19 If Mark Albrecht had sent you a
20 draft publication relating to patient warming
21 work at any point before March 24th of 2010,
22 and if you still had it, would you have
23 produced it to us?

24 A. I would have produced it.

25 Q. Okay. Do you believe, independently of what

1 NACHTSHEIM

2 this paper says, that you received any draft
3 publication from Mark Albrecht before
4 March 24th, 2010?

5 A. I don't believe I received anything before
6 then.

7 Q. Do you believe that this e-mail from Mark is
8 the first notice you received of this
9 particular study?

10 A. Well, again, if this -- if this -- I think
11 this study -- I -- I think this study was
12 evolved from some of the original
13 experimentation that I had talked about
14 previously that I had been observing.

15 Q. Let me ask this a different way. Have you
16 ever been to the lab more than -- had you
17 ever been to the warehouse where you observed
18 bubble testing more than once?

19 A. No, I don't believe so.

20 Q. I have another e-mail that might help us
21 place it in time.

22 A. I might have been there twice.

23 Q. Do you believe you were there twice or are
24 you not sure?

25 A. I seem to -- I'm just not sure. I --

1 NACHTSHEIM

2 Q. Do you have any recollection --

3 A. -- seem to remember having gone back again
4 and met him there, but I'm not sure that we
5 actually did work there. I just don't -- I'm
6 sorry, I don't recall.

7 Q. Okay. Okay.

8 (Whereupon, Exhibit 11 was
9 marked for identification.)

10 BY MS. GARCIA:

11 Q. If you would take a look at exhibit -- are we
12 at 11 now?

13 A. Yes.

14 Q. Okay. Exhibit 11 begins with an April 5th,
15 2010, e-mail from Mark to you saying, "You
16 could stop by either on Wednesday or Thursday
17 to observe the laminar flow lab in testing.
18 Let me know what might interest you. PS,
19 bring clothes that can smell like smoke,
20 because our smoking machine makes it stink
21 like cigarettes." Do you believe -- have I
22 read that correctly?

23 A. Yes.

24 Q. And do you believe this reflects an
25 invitation for you to come the first time to

1 NACHTSHEIM

2 the laminar flow location?

3 A. I do believe that, yes. I think this is the
4 first one.

5 Q. And so now that we have that date in mind,
6 would you agree that you had not been to the
7 lab to observe any laminar flow testing until
8 after the point when you received the
9 March 24, 2010, e-mail?

10 A. Yes.

11 Q. Knowing that, do you believe you had any
12 prior conversation with Mark Albrecht about
13 the study reflected in Exhibit 10 before you
14 received this e-mail from him?

15 A. I would think I had had some conversations
16 with him.

17 Q. Why do you say --

18 A. Because I -- well, I don't -- I mean, the way
19 he introduced this, "You can stop by to
20 observe the laminar flow lab and testing," I
21 think there's kind of an assumption in there
22 that I -- I kind of know what this is about
23 and -- and again -- and, again, I -- but I
24 just -- I'd never -- but I hadn't worked on
25 the project at this point. I think he might

1 NACHTSHEIM

2 have given me some introduction to what he
3 was doing, but I hadn't -- I hadn't done any
4 work on the project before this.

5 Q. Did you contribute at all to the design of
6 this study?

7 A. To this -- to the -- to the experiment design
8 of the study, yes.

9 Q. How would you have contributed to the
10 experiment design if this article came to you
11 drafted?

12 A. Well, I think usually Mark would -- would
13 say, Here's what I'm proposing, what do you
14 think. He -- and I just don't remember
15 exactly here, but he -- could I -- could I
16 read this for a second?

17 Q. Sure.

18 A. (Reviews document.) Yeah, so on the last
19 piece on -- on this Exhibit 11, Mark -- Mark
20 wrote to me and said, "Okay, this afternoon
21 will be fine, whenever you can make it.
22 Attached is the design. I used a full
23 factorial design with four replicates for
24 each treatment combination. For each
25 replicate there will be two measures and the

1 NACHTSHEIM

2 plan is to analyze the data with a repeated
3 measures model like the Pure Zone clinical."
4 So while Mark set the design up, usually what
5 he wants me to do is review it and say is
6 this making sense. That's all I meant by
7 contributing to the design.

8 Q. So to be clear, the piece that you just read
9 to me is from Exhibit 11 and it's dated
10 April 6th of 2010, which is after you
11 received the draft of the manuscript,
12 correct?

13 A. Correct.

14 Q. So the first time you would have received
15 from Mark an indication of the design other
16 than what's embedded within the manuscript,
17 is this April 6th e-mail?

18 A. I believe that's correct.

19 Q. Okay. And what he would be doing is asking
20 you to give him feedback on the design?

21 A. Yes.

22 Q. Do you recall having read this excerpt from
23 April 6th of 2010, whether you did or did not
24 have any comment on the design?

25 A. I recall having comment on the design

1 NACHTSHEIM

2 after -- I believe -- I believe when I went
3 out to see it, when I went out to see what
4 they were doing.

5 Q. What do you recall having to say?

6 A. Well, I seem to recall that -- this is vague
7 for me, but I seem to recall that I was
8 unhappy with the way the randomization was
9 being carried out, I didn't think it was
10 quite correct.

11 Q. Can you give me any more detail about what
12 you mean by that?

13 A. They may -- they might not have been changing
14 all the factors the way they should between
15 runs. I can't recall, but I -- I seem to
16 recall that I was -- that I said I don't
17 think is -- this is not good enough, this
18 needs to be redone, and I believe that -- and
19 I believe it was redone as a result of that,
20 and I think there was some discussion between
21 Mark and Dr. Augustine about that and I think
22 there was some sort of a restart on -- on it.

23 Q. Okay. I wonder if that would relate to --

24 (Whereupon, Exhibit 12 was
25 marked for identification.)

1 NACHTSHEIM

2 BY MS. GARCIA:

3 Q. -- Exhibit 12, by chance? Do you have any
4 idea if Exhibit 12 relates to what you just
5 described?

6 A. I think it does.

7 Q. So this is an e-mail sent by Mark to you two
8 days after -- well, actually, let me back up.

9 Exhibit 11 reflects an invitation of
10 you to stop by the lab on Wednesday or
11 Thursday, so that's the 5th, which is a
12 Monday, according to the e-mail, so that
13 means the 7th or 8th is the day you were
14 invited to come over.

15 A. Uh-huh.

16 Q. And then Thursday the 8th the e-mail to you
17 says, from Mark, "I laid out our results
18 today with Scott and he took the news well.
19 He wants us to really start understanding the
20 problem before pushing forward with research
21 publication efforts."

22 Do you believe Scott refers to
23 Scott Augustine?

24 A. Yes, I do.

25 Q. And do you -- do you believe this relates to

1 NACHTSHEIM

2 the randomization issue or do you have any
3 other sense of what this would relate to?

4 A. Again, I'm not positive it was just a
5 randomization, that's -- I'm just a little
6 vague about what it was I didn't like. I --
7 I think that I was -- I think I felt the way
8 that it was running, and maybe it was because
9 of the randomization, that it might not be
10 reproducible, and so I just felt they needed
11 to improve the way they were running the
12 experiment and the technique.

13 Q. And no more detail that you can think of
14 other than that? I'm not saying you should,
15 I'm just asking.

16 A. I just don't -- I -- I -- yeah, I just -- I
17 just don't recall. I just -- I think I felt
18 that -- again, I -- I think as I looked at
19 the technique, I didn't -- I was not happy
20 with it and I didn't think that it would be
21 sort of reproducible the way things were
22 going.

23 Q. Okay. You do say, if we look back at
24 Exhibit 10, you say, "Happy to help, I'll
25 have a look," and you did indicate an

1 NACHTSHEIM

2 interest in participating in the publication,
3 correct?

4 A. Yes.

5 Q. How did you envision your role then for that
6 study?

7 A. I saw my -- I saw my role at that time as, at
8 a minimum, overseeing the experimental design
9 and overseeing the analysis of the results.

10 Q. And when you say, "Overseeing," how do you
11 select that word? What do you mean by that?

12 A. Well, Mark is -- I would -- Mark -- I would
13 see Mark taking a first crack at things,
14 whether it's a design or an analysis, and
15 then usually I would then get it and look at
16 it and make suggestions for changes or say
17 this is -- this looks just fine.

18 Q. Okay. At this point in time did Mark have
19 already a master's degree in statistics?

20 A. You know, I don't -- I don't recall. I don't
21 believe he had a master's in statistics at
22 this point.

23 Q. I think I've seen somewhere that he does. Do
24 you believe he does currently have a master's
25 in statistics?

1 NACHTSHEIM

2 A. Oh, yes.

3 Q. Okay. Did you supervise his work to obtain
4 his master's degree?

5 A. I did.

6 Q. Do you believe this work may have been part
7 of that supervision?

8 A. No, this was not.

9 Q. This was for the Ph.D. process?

10 A. This particular work?

11 Q. Yes.

12 A. It had nothing to do with his academic.

13 This was just -- just for his boss,
14 Scott Augustine. It was for his work.

15 Q. So the work he was doing on -- the work that
16 you -- let me be clear. When you say, "This
17 work," do you include everything here
18 including Exhibits 4 and 5, that that had
19 nothing to do with his academic career?

20 A. Yes. I mean, it did not have anything to do
21 with his academic career.

22 Q. So the patient warming work was all in
23 connection with his employment and your role
24 was to supervise --

25 A. Yes.

1 NACHTSHEIM

2 Q. -- that?

3 A. Yes.

4 Q. And why did -- did you consider that he was
5 asking for a supervisor?

6 A. In terms of this work?

7 Q. Any of the patient warming work.

8 A. Yes, I -- I think -- yes, he -- he wanted to
9 work with an expert from the University of
10 Minnesota to be sure he was doing things
11 correctly.

12 Q. Did you -- and you believed that this work
13 ultimately fell within the umbrella of your
14 consulting agreement with Augustine?

15 A. Yes.

16 Q. And the reason I say Augustine is do you know
17 if your agreement was with Dr. Augustine
18 personally or with an Augustine company?

19 A. Oh, it was with an Augustine company, as I
20 recall.

21 Q. Did you -- were the e-mails and the
22 attachments that you produced to us in
23 response to the subpoena, documents that you
24 kept in the ordinary course of your work for
25 the Augustine company for which you were

1 NACHTSHEIM

2 consulting and for Mark Albrecht?

3 A. You mean if I kept them in an organized
4 fashion relating --

5 Q. Organized -- go ahead and finish your --

6 A. Because, no, it wasn't --

7 Q. It wasn't organized. No, I don't mean
8 organized. I said in the ordinary course.
9 You kept these e-mails as part of the
10 ordinary course of your work for
11 Mark Albrecht and for the Augustine
12 companies?

13 A. Yes.

14 Q. And do you believe that the e-mails and the
15 attachments that you produced to us
16 accurately reflect those that were originally
17 provided to you in the course of doing that
18 work?

19 A. Could you ask that again? I'm not sure --

20 Q. Yes.

21 A. -- what you're getting at.

22 Q. The documents and -- the e-mails and their
23 attachments, the documents that you provided
24 to us are an accurate set of those documents
25 that you kept during the course of your

1 NACHTSHEIM

2 work --

3 A. Yes.

4 Q. -- for Albrecht --

5 A. Yes.

6 Q. -- Mark Albrecht and the Augustine companies?

7 A. Yes.

8 Q. Thank you. I understand this is one of those
9 moments where we're reaching agreement, or
10 understanding, I should say, but we'll have
11 to try to separate our speaking so that Amy
12 will be able to take it down. Thank you.

13 When you wrote communications and
14 received communications, were those writings
15 made at or near the time when the work was
16 being done?

17 A. Yes.

18 Q. Do you know Dr. David Leaper?

19 A. No.

20 Q. Did you ever talk with Dr. David Leaper or
21 have any communication with him about the
22 work that is reflected in the manuscript
23 attached to Exhibit 10?

24 MR. SACCHET: Asked and answered.

25 THE WITNESS: Dr. Leaper may have

1 NACHTSHEIM

2 been on some of the e-mails, but I never had
3 direct communication with him.

4 BY MS. GARCIA:

5 Q. If you -- the way you -- start over.

6 The way you described your role
7 supervising Mark Albrecht's design work and
8 statistical analysis work, does that apply to
9 all of the patient warming work that you did,
10 including Exhibits 4 and 5?

11 A. Yes.

12 Q. Did you understand it to be your role to let
13 Mark Albrecht know if you thought there was
14 some type of issue or problem in the design
15 of the study?

16 A. Yes.

17 Q. And, likewise, in the statistical analysis
18 that he had planned for the study or had
19 conducted?

20 A. Yes.

21 Q. Do you have any substantive knowledge about
22 the comparative effectiveness of a forced-air
23 warming device versus a convective-warming
24 device? Or, I'm sorry, I said that wrong.

25 Do you have substantive knowledge of

1 NACHTSHEIM

2 the effectiveness comparatively between any
3 patient-warming devices at keeping a patient
4 warm?

5 A. I do not.

6 Q. Do you have any substantive knowledge about
7 the different airflow patterns that are used
8 in operating rooms?

9 A. And by, "Substantive" -- by, "Substantive
10 knowledge," do you mean at the mechanical
11 level or --

12 Q. Yes.

13 A. No, I don't.

14 While you're looking, may I grab
15 some more water?

16 MS. GARCIA: Let's just take a --
17 let's take a short break. I could use a
18 break too.

19 THE WITNESS: Okay.

20 THE VIDEOGRAPHER: We're going off
21 the record at 10:24 a.m.

22 (Whereupon, a brief recess
23 was taken.)

24 THE VIDEOGRAPHER: This is video
25 number 2 in the deposition of Christopher

1 NACHTSHEIM

2 Nachtsheim. Today is November 29th, 2016.

3 We're going back on the record at 10:35 a.m.

4 BY MS. GARCIA:

5 Q. Thank you. I'm going to ask just a few more
6 questions to take a break from documents
7 clarifying to be sure that I understand the
8 scope of your expertise.

9 Did you contribute medical or
10 surgical expertise to either the McGovern or
11 Belani studies, Exhibits 4 or 5?

12 A. No.

13 Q. Do you have any medical, surgical or
14 infectious disease training?

15 A. No.

16 Q. Your Ph.D. is, I understand it, in operations
17 research?

18 A. Yes.

19 Q. Have you ever consulted with medical device
20 manufacturers about product design or
21 performance?

22 A. Yes.

23 Q. That's the work you were talking about
24 earlier?

25 A. Yes.

1 NACHTSHEIM

2 Q. Okay. The statistical analysis related to,
3 in each case, a medical product?

4 A. Yes, yes. Either statistical design or
5 analysis or both.

6 Q. Sometimes you were consulting about the
7 design of a study?

8 A. Exactly.

9 Q. Have you ever consulted with a hospital about
10 the design or ventilation of an operating
11 room?

12 A. No.

13 Q. Do you know anything about how a surgical
14 operating room or surgical theater typically
15 is set up in the United States?

16 A. Only what I've learned working with Mark
17 and -- and -- and -- and -- and the
18 colleagues on these papers, just -- just a
19 little bit about drapes, things of that
20 nature, but that all came from -- from my
21 exposure on these studies.

22 Q. Okay. Before you began to work on Exhibits 4
23 and 5 -- before the began to work on the
24 studies that were reflected in Exhibits 4 and
25 5, you knew nothing about --

1 NACHTSHEIM

2 A. I knew nothing --

3 Q. -- operating rooms?

4 A. I knew nothing.

5 Q. Thank you. We'll get back into the rhythm of
6 waiting for each other to finish.

7 Did you happen to see the -- let me
8 start over.

9 Did you ever observe any of the
10 hospital settings where work took place that
11 is captured in Exhibits 4 and 5?

12 A. No.

13 Q. Did you help to decide how that experimental
14 environment would be set up for either
15 Exhibit 4 or 5?

16 A. No.

17 Q. And if we would look at Exhibit 5, which is
18 the Belani study -- no, I'm sorry, for both
19 studies, both studies reflect also -- both
20 studies reflect -- let me start over again.

21 Both studies reflect that there were
22 bubble experiments conducted. Do you know
23 where the bubble experiments were conducted
24 for either study, Exhibits 4 and 5?

25 A. Well, I know where the hospitals were, if

1 NACHTSHEIM

2 that's -- is that what you mean?

3 Q. Sure. That would be helpful.

4 A. I mean, there was one at the
5 University of Minnesota and one at -- in the
6 United Kingdom.

7 Q. For the University of Minnesota, do you know
8 what hospital it was?

9 A. I don't.

10 Q. Do you understand that the bubble experiment
11 was conducted in only one hospital
12 environment or in more than one?

13 A. When you say, "The bubble experiment" --

14 Q. Any bubble experiment.

15 A. Any bubble experiment?

16 Q. For Exhibit 5.

17 A. For -- oh, for Exhibit 5. Okay.

18 Q. Which I believe is the study that references
19 a University of Minnesota hospital.

20 A. I -- my understanding was it was done in one
21 site.

22 Q. But you don't know which hospital?

23 A. I do not.

24 Q. And you don't know anything about how it was
25 set up?

1 NACHTSHEIM

2 A. I do not.

3 Q. For Exhibit 4, which is the McGovern study,
4 do you know anything about where the bubble
5 experiments were conducted there?

6 A. I don't have any particular knowledge about
7 those.

8 Q. Did you have any input into the selection of
9 neutral buoyancy detergent bubbles as a way
10 to measure air movement in the tests?

11 A. I did not.

12 Q. And were you present for any of the
13 experimental testing that became part of
14 Exhibits 4 or 5?

15 A. I was not.

16 Q. Did you ever prepare an initial draft of any
17 patient warming abstract or article?

18 A. No.

19 Q. And by, "Prepare," I mean write. Was that
20 clear to you?

21 A. Yes, it was. Yes, it was.

22 Q. You did review both the McGovern and the
23 Belani articles before they were submitted
24 for publication?

25 A. I did, yes.

1 NACHTSHEIM

2 Q. Did you read the complete manuscripts that
3 you were provided?

4 A. Yes.

5 Q. Were you given the opportunity to make edits
6 to both of these articles, Exhibits 4 and 5,
7 before they were submitted for publication?

8 A. Yes.

9 Q. Did you make any edits that you felt were
10 needed?

11 A. Yes.

12 Q. Did you feel comfortable -- oh, go ahead.

13 A. I mean, they were minor edits --

14 Q. Okay.

15 A. -- as I recall.

16 Q. The edits you made were minor edits?

17 A. Yes.

18 Q. Did you feel comfortable enough with
19 Mark Albrecht that if you felt some type of
20 revision was needed to either one of papers
21 Exhibits 4 or 5, you would feel comfortable
22 raising that?

23 A. Yes.

24 Q. Is it standard in your profession for authors
25 to identify places where their work has

1 NACHTSHEIM

2 limits?

3 A. Did you say places where their work has
4 limits?

5 Q. Yes.

6 A. I don't know what you mean.

7 Q. Is that not a clear question?

8 A. It's not a clear question to me.

9 Q. Is it standard in your profession for authors
10 to identify limits to their work and to the
11 generalizability of their work?

12 A. Yes.

13 Q. And, in fact, Exhibits 4 and 5 both reflect
14 limitations expressed by the authors?

15 A. Yes.

16 Q. Did you review those?

17 A. I did, yes.

18 Q. And if you disagreed with any of the
19 expressed limits, would you have raised that?

20 A. Yes, I would have.

21 (Whereupon, Exhibit 13 was
22 marked for identification.)

23 BY MS. GARCIA:

24 Q. Exhibit 13 is an April 9th, 2010, e-mail from
25 Mark to a group of people including you; is

1 NACHTSHEIM

2 that correct?

3 A. (No response.)

4 Q. Did you hear my question?

5 A. No, I'm sorry, I didn't.

6 Q. That's okay. I thought you may not have.

7 Exhibit 13 is an April 9, 2010,
8 e-mail from Mark Albrecht to a group of
9 people including you; is that correct?

10 A. That's correct.

11 Q. This is, if you'll recall by reference to
12 Exhibits 11 and 12, within a few days of when
13 you visited the lab, correct?

14 A. Correct.

15 Q. There is a beginning address of capital A,
16 capital D. Do you know what that means?

17 A. I do not.

18 Q. The statement that Mark Albrecht makes is
19 that, "Randy, Scotty, Keith and I examined
20 the flow uniformity in the laminar flow
21 laboratory today with smoke tracers. We now
22 know why our results have been coming out so
23 goofy. There are jets and stagnation points
24 all over the flow field. Further, even a
25 portion of the plenum had partially collapsed

1 NACHTSHEIM

2 and was fully blocked. Scott would like
3 Randy and Scotty to reconstruct the blower
4 plenum on Monday. I'll help as best I can."

5 Do you know what they're referring
6 to in any more detail than this provided
7 here?

8 A. Not in any more detail than this.

9 Q. Do you recall talking to Mark Albrecht about
10 this?

11 A. I think this relates to my point earlier that
12 when I watched -- when I watched the
13 experiment I -- I just -- I was unhappy with
14 the way it was being run, the order it was
15 being run, and I was unhappy with the -- I
16 was unhappy with the experimental setup. As
17 I said, I didn't think it was reproducible.
18 And I didn't know -- I didn't necessarily
19 know why, I just didn't think it was
20 reproducible.

21 Q. You think that your concern about
22 reproducibility had to do with airflow and
23 the reproducibility of airflow?

24 A. I would conclude that by looking at this.
25 They were going to look at what was wrong,

1 NACHTSHEIM

2 what was going on that was leading to these
3 results that were not sort of reproducible.
4 And I -- when I saw this e-mail, I assume
5 that that was -- that was their solution to
6 the problem.

7 Q. You have a recollection sitting here today of
8 seeing this e-mail and that connecting in
9 your mind to whatever you identified as a
10 problem?

11 A. You know, I -- yes, I do have a recollection
12 of seeing this e-mail, but I may have -- my
13 recollection may be -- this was in my group
14 of e-mails, I think.

15 Q. Yes.

16 A. And -- and what I do -- what I most remember
17 is talking to Mark at some point. And I
18 thought it was actually on a phone call or
19 maybe in person and him saying, Well, we kind
20 of have to rebuild this thing, we had some
21 problems with -- with it and so that's going
22 to take some time.

23 Q. How would you know in the couple of hours
24 that you were there in the warehouse that
25 there was going to be an issue with

1 NACHTSHEIM

2 reproducibility? What were you observing?

3 A. You know, I think what I was observing -- I
4 don't recall for sure. It seems to me what I
5 was observing was running maybe the same test
6 condition a couple of -- twice and -- and
7 seeing different kinds of results or
8 seeing -- seeing different things and -- and
9 I -- that would be a way where I would say --
10 I mean, that would be a reason I would say I
11 don't think is reproducible, it doesn't seem
12 to be reproducing, so something seemed amiss,
13 that's all.

14 Q. And then if we go down to the second
15 paragraph, it says, "As a second" -- on
16 Exhibit 13. The second paragraph on
17 Exhibit 13 --

18 A. Okay.

19 Q. -- says, "As a second point, Scott and I
20 think it would be a prudent idea to delay the
21 testing by two to three weeks in Europe given
22 that all of the data we have collected has
23 been flawed to date. We need to get a good
24 grip of the situation in a properly
25 functioning ventilation field before doing

1 NACHTSHEIM

2 any experiments in an OR at this point."

3 Is that consistent with what you've
4 just been saying?

5 A. Yes.

6 Q. The same issue?

7 A. Yes.

8 Q. Do you know what was done in the warehouse to
9 try to address this issue with the
10 ventilation field?

11 A. I don't know -- I don't have the particulars.
12 My impression was it was almost completely
13 rebuilt.

14 Q. The external building or the --

15 A. No, the internal -- the simulated -- the
16 simulated operating room.

17 Q. Did the external walls of the warehouse
18 change, to your knowledge?

19 A. No.

20 Q. Do you know anything about the
21 reproducibility or validity of the airflow
22 within the simulated laboratory once that
23 construction was done?

24 A. Actually, no, I was not -- I never saw the
25 reconstructed room. I never saw any

1 NACHTSHEIM

2 experiments going on in that reconstructed
3 room.

4 Q. Do you believe the room was reconstructed?

5 A. I believe it was.

6 (Whereupon, Exhibit 14 was
7 marked for identification.)

8 BY MS. GARCIA:

9 Q. Exhibit 14 is an April 26th, 2010, e-mail
10 from Mark Albrecht to Robin Humble,
11 Scott Augustine and you; is that correct?

12 A. Yes.

13 Q. Who is Robin Humble?

14 A. I don't know.

15 Q. Mark says, "Bubble machine came in today,"
16 and emphasizing, "It is the tool we have been
17 looking for." And then he says, "In two
18 hours we figured out how to create a very
19 compelling demo of the laminar flow
20 disruption as follows," and then he describes
21 particular steps about draping and
22 introducing bubbles; is that correct?

23 A. Yes.

24 Q. Did you have any discussion with Mark about
25 this?

1 NACHTSHEIM

2 A. I did not.

3 Q. Did you have any input or involvement in
4 figuring out how to create this situation?

5 A. I did not.

6 Q. Do you know how many different arrangements
7 they tried of draping and placement of a
8 surgeon and introduction of the bubbles
9 before they landed on this one?

10 A. I do not.

11 Q. Did you ever ask Mark about that?

12 A. No, I did not.

13 Q. Do you have any idea how true to an actual
14 operating room or surgical setting this
15 particular arrangement of factors is?

16 A. I do not know that.

17 Q. And do you know if any of the other setups
18 they tried during that two hours were more
19 realistic in terms of reflecting an operating
20 room?

21 A. I am unaware of that.

22 Q. This is not something you asked about?

23 A. No, I did not.

24 Q. Were you ever involved in creating or proving
25 or reviewing any videotaped demonstration of

1 NACHTSHEIM

2 air movement for posting on the Internet?

3 A. I was not involved in producing or reviewing
4 those. I was -- I believe I was copied on --
5 on them at some point to say here's a -- it
6 came across my e-mail so I could go view it,
7 but I was not involved in creating it.

8 Q. And you were not involved in confirming that
9 any situations depicted in any videotapes
10 showing air movement are valid or accurate or
11 reproducible?

12 A. No, I was not.

13 Q. Did you have any involvement in -- let me ask
14 that differently.

15 Did you any -- did you have any
16 conversations with Mark Albrecht or anyone
17 else about how they decided the setup in the
18 hospital settings that are reflected in
19 Exhibits 4 or 5?

20 A. I -- I was not involved in those setups.

21 Q. Do you know what they did to determine what
22 would be the way they set up the mannequin or
23 the draping or where they introduced the
24 bubbles?

25 A. No, I do not.

1 NACHTSHEIM

2 Q. Do you know if they did any similar exercise
3 of trying for a couple of hours to find the
4 perfect setup?

5 A. I'm not aware of that.

6 Q. Do you know if in connection with either the
7 McGovern or Belani papers, they tried
8 multiple different setups before landing on
9 the one that was reflected in the paper?

10 MR. SACCHET: Asked and answered.

11 THE WITNESS: I'm not aware of
12 that.

13 BY MS. GARCIA:

14 Q. Is that something you asked about?

15 A. I did not.

16 Q. Did you consider it any part of your role to
17 do any investigation about the validity or
18 reproducibility of the operating room setups
19 that were used for the bubble experiments in
20 either Exhibit 4 or 5?

21 MR. SACCHET: Asked and answered.

22 THE WITNESS: Yeah, I didn't --
23 could you ask it again? You're asking did
24 I -- was it my responsibility -- I'm sorry.

25 MS. GARCIA: If I could just have

1 NACHTSHEIM

2 the question read back, that would be
3 terrific. Thank you.

4 (Whereupon, the last question
5 was read by the court reporter.)

6 THE WITNESS: So I didn't consider
7 it my role to be involved in the physical
8 setup of the -- of the experiments. As part
9 of the design and the statistical analysis,
10 one can determine reproducibility and -- and
11 that's part of my job in terms of analyzing
12 the data.

13 BY MS. GARCIA:

14 Q. That would be once the data is generated?

15 A. That's right, after the data has been
16 generated.

17 Q. And that would be based on a particular setup
18 in the operating room?

19 A. Correct.

20 Q. But in terms of the fidelity in the operating
21 room setup used for the experiment versus an
22 actual operating room, did you consider it
23 any part of your role to investigate that?

24 A. I -- I did not. When things moved to the
25 operating rooms and there were -- the

1 NACHTSHEIM

2 physicians involved, I expected that that was
3 kind of in their realm of expertise.

4 Q. Having seen that Mark Albrecht spent a couple
5 of hours in the laminar flow lab landing on
6 something that would provide the perfect
7 demo, did you have any concern about what was
8 done in these operating rooms?

9 A. I did not.

10 Q. You never asked him about it?

11 A. I never did.

12 Q. And who did you understand was providing the
13 medical expertise about the way that
14 operating rooms would be constructed for the
15 bubble experiments reflected in Exhibits 4
16 and 5?

17 A. I can't recall the -- well, the -- I can't --
18 there were e-mails that came across talking
19 about the physicians that would be involved
20 in the setup and the use of the -- and
21 arranging for the operating room and so
22 forth. I don't remember exactly which people
23 on these papers did that, but that was my
24 under -- but I just -- I guess I just assumed
25 there were a few -- that these physicians who

1 NACHTSHEIM

2 participated in the experiment and got access
3 to the operating rooms were helping with the
4 setup.

5 Q. Do you know if the bubbles were introduced
6 under the drape in the same way when the
7 HotDog device was being tested as when the
8 Bair Hugger device was being tested?

9 A. That -- my assumption is that they were
10 introduced under the same -- the same -- the
11 same circumstances. I assume they were the
12 same.

13 Q. And why would you assume that?

14 A. Good experimental practice.

15 Q. Okay. It would be good experimental practice
16 for everything else to be held constant --

17 A. That's right.

18 Q. -- except for the warming device?

19 A. Yes. Well, when you run an experiment
20 sometimes you may be changing -- you may be
21 changing two factors at the same time,
22 depending on the randomization and how that
23 works, but everything else should be held
24 constant.

25 Q. In this -- in these particular experiments

1 NACHTSHEIM

2 reflected in Exhibits 4 and 5, would you
3 believe that good experimental practice
4 should have included bubbles being introduced
5 under the drapes in the same way for both the
6 warming devices being tested?

7 A. Yes.

8 Q. What do you understand the point of the
9 bubble experiments was for these studies?

10 A. I think the point was to investigate if
11 the -- the waste heat generated from the
12 Bair Hugger had any effect on the -- the flow
13 of the air, if it would interrupt the sort of
14 downward, I don't know what they call that,
15 but the laminar flow, I guess, if there would
16 be disruptions as a result of the -- of the
17 Bair Hugger.

18 Q. When you say, "Waste heat," what do you mean?

19 A. What I mean, I just mean the -- my
20 understanding is that the -- well, the
21 Bair Hugger takes warm air in and blows it
22 out down onto the patient and into the room,
23 that's all I mean.

24 Q. When you say, "Blows it out, you moved your
25 hands down. Do you have any understanding

1 NACHTSHEIM

2 about where on the device the warm 'air is
3 being blown from"?

4 A. Only from an operation that I had about a
5 year ago or two years ago where I was -- I
6 think I was put under a Bair Hugger for that.

7 Q. Does that give you any understanding of --

8 A. No.

9 Q. Do you --

10 A. No, no.

11 Q. Do you, even today, have any understanding
12 about where in the Bair Hugger device air is
13 blown from that you're talking about that
14 might be hot air?

15 A. I don't have good knowledge of that, no. You
16 know, my -- just my understanding was that
17 it -- when I say down, it blows it onto the
18 patient. I mean, the point is to keep the
19 patient warm. So, no, I don't have
20 particular knowledge about how that works.

21 Q. In your mind, is the point of the
22 observation, if it were well done, to be
23 accurately -- accurately reflecting a real
24 operating room environment?

25 A. Yes.

1 NACHTSHEIM

2 Q. Would you consider it good experimental
3 practice to spend a couple of hours moving
4 things around to see how you can demonstrate
5 the most difference between the two devices
6 and the airflow?

7 A. No, I wouldn't consider that good practice.

8 Q. Why not?

9 A. Because I think that moves away from -- you
10 know, we just said what we're trying to do is
11 simulate the -- the real conditions and we're
12 not trying to bias our results, so I think
13 you want to have the simulation, and it is a
14 simulation as real as possible --

15 Q. When you --

16 A. -- as -- as representative as possible.

17 Q. Thank you for that clarification, that's a
18 good word.

19 Would you expect the experimental
20 setup to be determined in advance before the
21 experiment was run based on what is
22 representative for the environment to which
23 they were conducting the test?

24 A. Yeah. Yes, I would expect that.

25 Q. Is it your understanding that Exhibits 4 and

1 NACHTSHEIM

2 5 report on the results of experiments
3 actually conducted in the hospital settings
4 identified in the papers?

5 A. Yes.

6 Q. Was that always your understanding that
7 that's what would be done?

8 A. That there would be an experiment carried out
9 in a hospital operating room and we would
10 report the results on that.

11 Q. Yes.

12 A. That was my understanding.

13 Q. Would you consider it appropriate to use
14 pictures of the bubbles in the operating room
15 setting and combine that with quantitative
16 data from the warehouse testing to provide
17 quantitative results for either Exhibits 4 or
18 5?

19 MR. SACCHET: I'm going to object
20 to the form.

21 THE WITNESS: I think it depends
22 on how it's reported. I -- I certainly
23 wouldn't report it -- I wouldn't -- wouldn't
24 report it as part of the write-up on the
25 analysis of a particular -- of the experiment

1 NACHTSHEIM

2 that went on in the operating room, but --
3 but there -- in any -- in -- in any paper
4 such as this there are -- there may be a
5 justification for bringing up other -- other
6 data that's sort of related.

7 MS. GARCIA: Okay.

8 BY MS. GARCIA:

9 Q. It would depend on how it's written up?

10 A. It would depend on how it's written up.

11 (Whereupon, Exhibit 15 was
12 marked for identification.)

13 BY MS. GARCIA:

14 Q. Exhibit 15 is an e-mail from Mark Albrecht to
15 Scott Augustine and you and Robin Humble on
16 May 25th, 2010, with an abstract attached; is
17 that correct?

18 A. Yes.

19 Q. What Mark says is, "Scott and Chris, here is
20 a draft of one of two abstracts I'm going to
21 submit on June 1. Here is my plan: Chris,
22 I'm planning on making you an author on both
23 abstracts, this is the first"; is that
24 correct?

25 A. Yes.

1 NACHTSHEIM

2 Q. If you would look at the attached abstract,
3 it talks about evaluation of filtration
4 adequacy and internal contamination
5 detection. Do you recall ever working on a
6 study like this? And by, "Working on," I
7 mean providing any type of consultation or
8 advice.

9 A. I did not work on this.

10 Q. Was this e-mail from Mark on May 25th the
11 first time you learned of this study?

12 A. Yes. Well, I believe so. Yeah.

13 Q. When you say, "With confidence," as I am
14 interpreting it, you did not work on this --
15 I take it one thing you mean is you were not
16 involved in any publication reflecting this
17 work?

18 A. Correct.

19 Q. You don't recall providing any advice ever
20 about either the set up or the -- the design
21 or the statistical analysis for this study?

22 A. I don't. I don't recall doing that. I
23 remember reading this abstract and thinking I
24 would maybe be involved, but I don't -- I
25 don't recall actually be involved in this

1 NACHTSHEIM

2 study.

3 Q. Do you know what happened with it?

4 A. Not really. I'm aware there was some
5 publications. I don't know if it came from
6 this or not, but I'm aware there were
7 publications having to do with contamination
8 and so forth, maybe in the hoses and inside
9 the -- the --

10 Q. Do you recall -- oh, I'm sorry, I didn't mean
11 to cut you off.

12 A. -- the blower.

13 Q. The -- the blower?

14 A. Yeah.

15 Q. Do you recall why it was that you weren't
16 involved in that work?

17 A. I don't.

18 Q. Do you recall whether you declined or --

19 A. I don't think I declined. I think -- I --
20 I -- I just don't remember what happened.

21 Q. Okay. If we look back at the e-mail, you've
22 asked Mark to show you the analysis, and on
23 the next page he says that he will send it.
24 He also, in the May 26th e-mail that's the
25 last one on the second page, says, "I'll need

1 NACHTSHEIM

2 your approval on the stats for the abstract
3 we are submitting by Tuesday at the latest,"
4 and in parenthesis, "Data collection is on
5 Sat.," meaning Saturday and Sunday.

6 Can you help me understand how that
7 reference to data collection fits with the
8 fact that there's an abstract attached to
9 this e-mail?

10 MR. SACCHET: Object; calls for
11 speculation.

12 THE WITNESS: I can't comment on
13 it. I really don't -- I really don't know.
14 He's clearly already done what appears to be
15 some data analysis, but then he's talking
16 about data collection, so I'm a little -- I'm
17 not -- I'm not clear on what's -- what the
18 sequence of events are here.

19 MS. GARCIA: Okay.

20 BY MS. GARCIA:

21 Q. Are you ever aware of a situation where Mark
22 provided you with -- Mark Albrecht provided
23 you with an abstract for work that had not
24 yet been done?

25 A. No, unless it was talking about plans to do

1 NACHTSHEIM

2 it or, you know, what was -- what was
3 intended, no, I'm not aware of that.

4 Q. Is it typical, in your profession, to write
5 up an abstract including results before
6 you've actually done the work?

7 A. No.

8 Q. And why not?

9 A. If you're giving results -- I guess that's
10 not ethical if you're giving results that --
11 if you're making things up, if that's what
12 you're kind of what you're talking about.

13 Q. Well, that would be if you published it. I'm
14 talking about drafting it even.

15 A. It's just not -- that's not -- that's just
16 not done unless there were some proto --
17 proto -- some -- some -- I've done things
18 where I've run some small experiments and
19 said, Here's what we think things are going
20 to look like, I suppose, but we still have to
21 run the full -- the full simulations to get
22 the actual data, so here's a draft of what
23 this could look like, but certainly, you
24 know, not for publication.

25 I'm talking about some -- some sort

1 NACHTSHEIM

2 of prototype research that you might have
3 done that's kind of quick and dirty, say,
4 Well, I think this is what it's going to look
5 like, let's write this up and see what it
6 looks like, but we still have to carry out
7 the real study.

8 Q. Sure. Thank you.

9 (Whereupon, Exhibit 16 was
10 marked for identification.)

11 BY MS. GARCIA:

12 Q. I've marked as Exhibit 16 a May 29, 2010,
13 e-mail from Mark Albrecht to Mike Reed,
14 Scott August -- Scott Augustine, A. Deibel is
15 the e-mail address, you, and Robin Humble
16 again. Do you know who A. Deibel is?

17 A. I don't.

18 Q. Both Robin Humble and, I believe it is
19 Andreas Deibel, have Aug Biomed addresses.
20 Did you ever deal with anyone at
21 Augustine Biomedical other than occasionally
22 Scott Augustine and Mark Albrecht?

23 A. I did not. You know, as I said, I might
24 have -- I might have met this person at that
25 social gathering I talked about. There

1 NACHTSHEIM

2 were -- there were people from Europe at
3 that, and I'm not -- I don't know for sure,
4 but this might have been one of those
5 persons.

6 Q. Tell me more about how that gathering came to
7 be.

8 A. I think there were some people and maybe
9 physicians that were going to be in town, and
10 I think Scott felt it was a nice opportunity
11 to sort of get everybody together and -- and
12 so had -- had a number of us over to his
13 house in the evening.

14 Q. I have been assuming that you mean Minnesota,
15 but I should ask, where is his home?

16 A. It's in Minnesota.

17 Q. Okay.

18 A. It's in western -- the western suburbs of the
19 Twin Cities.

20 Q. And there were some physicians there from
21 Europe?

22 A. Well, there was -- there were -- yes, I
23 believe so. There were certainly people --
24 there was -- there were one or two -- maybe
25 even just one. There was at least one person

1 NACHTSHEIM

2 there from Europe.

3 Q. The collection of people at Scott Augustine's
4 house that evening included authors on
5 Exhibits 4 and 5, people who were authors on
6 Exhibits 4 and 5?

7 A. You know, for sure, I was there.

8 Q. True.

9 A. I think there were -- yes, I think there were
10 one or two others. I'm just very bad at
11 names and so -- you know, if they had given
12 me their social security numbers, I'd -- I'd
13 remember them.

14 Q. You'd remember them. Scarey.

15 But are you -- are you --

16 A. I'm just kidding.

17 Q. No, that's fine.

18 A. I'm not -- I'm -- I'm -- sorry, I'm not good
19 with names.

20 Q. You had previously said that the people who
21 were there, though, were -- were gathered as
22 people who had been working on the patient
23 warming research?

24 A. Yes. And I think there were also just other
25 employees from Scott's company.

1 NACHTSHEIM

2 Q. And you're not recalling any conversations
3 about the research or the publications?

4 A. I'm not recalling any at that -- I'm not
5 saying there wasn't, I'm just not recalling.

6 Q. Do you recall there being any formal
7 presentation or kind of announcement of good
8 news?

9 A. No.

10 Q. This e-mail references, "Nearly completed
11 drafts of two abstracts that Mark Albrecht
12 would like you and Mike Reed to be a part
13 of." Do you see that in the beginning of the
14 e-mail?

15 A. I do.

16 Q. Was this e-mail communication on May 29th the
17 first time that you had any notice about
18 these studies?

19 A. Well, I guess except Exhibit 15, right,
20 the -- I think -- I don't -- this may be --
21 I'm thinking that --

22 Q. I think you're right. And if you look at
23 page 213, there is an abstract about the
24 filtration adequacy.

25 A. Right.

1 NACHTSHEIM

2 Q. Okay.

3 A. And isn't that the same -- is that the same
4 one? It looks familiar.

5 Q. It sure may be.

6 A. (Reviews document.) It's a little bit
7 changed, but it looks like maybe a new
8 version of that.

9 Q. And then the last page of Exhibit 16 is
10 another abstract and talks about, "Laminar
11 ventilation being tested in an orthopedic
12 operating theater."

13 A. I'm sorry, could you give me the number,
14 the page, is it --

15 Q. 223.

16 A. Oh, I'm sorry, 223.

17 Q. It's the last -- it should be the last page
18 in the exhibit.

19 A. Mine goes on to 277.

20 Q. Oh, that might be an error. Can I see the
21 exhibit?

22 A. I think there are two hooked together maybe.
23 (Hands document.)

24 Q. Thank you.

25 MR. SACCHET: Do you want it back?

1 NACHTSHEIM

2 MS. GARCIA: Ah, there is an
3 error. Okay, could I --

4 MR. SACCHET: Do you want it back?

5 MS. GARCIA: Yeah. Thank you.

6 MR. SACCHET: (Hands document.)

7 BY MS. GARCIA:

8 Q. All right. Now try the last page.

9 A. 223?

10 Q. Yes. I was going to ask if you have any
11 recollection of this work from an earlier
12 time?

13 A. I do not.

14 Q. And, actually, do you believe by looking at
15 the abstract that's on page 223, can you
16 determine one way or another whether this
17 work being described here ultimately became
18 Exhibit 4?

19 MR. SACCHET: Asked and answered.

20 MS. GARCIA: Can I ask you to just
21 stick with objections to form, please.

22 MR. SACCHET: Sure.

23 MS. GARCIA: That would be great.

24 THE WITNESS: Yeah, this does look
25 like it led to one of these, I'm not sure

1 NACHTSHEIM

2 which. Yes.

3 BY MS. GARCIA:

4 Q. And on what basis are you saying it looks
5 like it became one of those?

6 A. Well, the -- where he says -- or where the
7 abstract says, "Replicated factorial
8 experiment was used for the two different
9 types of blanket, FAW or CFB," and then the
10 anesthesia drape position at 1.5 meters and
11 2.0 meters, that's -- that's exactly the
12 experiment that was carried out in one or
13 both of these studies.

14 Q. Do you want to take a look at them --

15 A. Sure, yeah.

16 Q. -- and see which one or both?

17 A. Yes.

18 Q. That would be great. Thank you.

19 A. So this corresponds to the -- the McGovern
20 paper.

21 Q. Exhibit 4?

22 A. I'm sorry, I shouldn't be looking at my
23 copies, but, yes, I believe so. Hold on.

24 (Reviews documents.) There we go.

25 Exhibit 4.

1 NACHTSHEIM

2 Q. Thank you.

3 If you'd turn to the first page of
4 the e-mail on Exhibit 16, after he says,
5 "Okay," in the middle of page, there is a
6 reference to the, "First crud and bug story
7 about inadequate filtration."

8 A. Uh-huh.

9 Q. That is the abstract for which you never
10 became a part of the study?

11 A. Correct.

12 Q. And then second he talks about, "The work
13 completed today with the bubble helium
14 pictures," and then he gives you a note on
15 the statistics and says, "There was a data
16 degeneracy problem in estimating a full ANOVA
17 model because the counts for multiple
18 treatment combinations were zero. Instead, I
19 did separate Poisson models for specific
20 tests of interest. That worked just fine and
21 should be defensible. That is why there are
22 three attached model printouts for the second
23 abstract." That comment relates to the
24 McGovern study Exhibit 4?

25 A. Yes.

1 NACHTSHEIM

2 Q. And can you explain to me what that means?

3 A. Sure. The -- I've got to think about how he
4 was doing the ANOVA model.

5 Q. If it would help you, the three model results
6 are actually within Exhibit 16 in the middle.
7 I have included within Exhibit 16 the three
8 results that he references.

9 A. He was doing the -- the different models
10 considered were logistic regression versus --
11 and Poisson regression. And in logistic
12 regression, you're looking at failures and
13 successes and/or percentages, things like
14 that. If you have a case where there's never
15 any failures, everything is just all
16 successes, then that's what's called a
17 degeneracy problem. And so the alternative
18 with the Poisson model, which is just counts,
19 zero is fine.

20 Q. Okay. So putting that in the context of this
21 study, would that relate to the bubble
22 counting experiment or to infection data?

23 A. My initial impression was this was for the
24 bubble, but can I -- I better look.

25 Q. Sure.

1 NACHTSHEIM

2 A. Maybe I better have a look just to be sure.

3 (Reviews document.)

4 Q. There are also data sheets in here
5 referencing ether. I don't know if that
6 helps or not.

7 A. (Reviews document.) I'm -- it's interesting,
8 because the first study seems to be different
9 than the others. I mean, there's -- there's
10 four different models being run here.

11 Q. Okay.

12 A. The first one seems to be dealing with filter
13 types.

14 Q. Okay. And perhaps that relates to the other
15 abstract?

16 A. That -- right, that would -- that would have
17 to do with the crud and bug, I think.

18 Q. Okay. So the other three --

19 A. The other three are -- are different ways of
20 analyzing the -- the Bair Hugger versus the
21 HotDog, it looks like that's all that's being
22 done here.

23 Q. And, actually, now that I look at it, the
24 dependent variable is bubble count, right?

25 A. Right.

1 NACHTSHEIM

2 Q. So these -- are -- is it your understanding
3 these models to -- is it your understanding
4 that these models relate to the bubble
5 counting experiment?

6 A. The third, fourth and fifth --

7 Q. Yes.

8 A. -- analyses, I would -- well, I would think
9 so.

10 Q. Okay. How do you randomize in a bubble
11 study? What are you randomizing?

12 A. Well, it's -- it's -- so there was a -- it
13 was a 2 by 3 factorial design, and the --
14 the -- the 3 level factor was the height of
15 the -- the drape, and the 2 level factor was
16 the -- whether the -- the Bair Hugger versus
17 the HotDog or the two -- two different types
18 of blankets. And so all randomization means
19 is since there were going to be essentially
20 two replicates of the experiment, that means
21 there are going to be 12 runs, 2 by 3's, so
22 there's -- there's 6 combinations.

23 Q. A device with a table height --

24 A. Yeah.

25 Q. -- three different ways --

1 NACHTSHEIM

2 A. Yeah. Yes, so two times three ways of doing
3 that.

4 Q. And then they were going to replicate the
5 whole thing once more?

6 A. They were going to do it one more time. So
7 it's 12 setups, and so basic -- basically,
8 one lists the 12 setups and randomizes the
9 order.

10 Q. In which you combine the devices with the
11 table heights?

12 A. Exactly.

13 Q. And what are the failures or successes that
14 are being counted, what -- what is -- what
15 would be a failure or a success for purposes
16 of considering an ANOVA model?

17 A. Well, if -- if -- so if a logit analysis is
18 being done, then you're right, there has to
19 be a success and a failure, and I don't -- I
20 don't know for sure what's going on here,
21 because I'm -- I'm -- I'm just thinking about
22 bubble counts. It could be that -- I'm
23 speculating, but it could be that one is
24 saying, well, if there were bubbles that got
25 into a particular region, yes or no, that's a

1 NACHTSHEIM

2 success or a failure. But that's complete
3 speculation. I don't know exactly what --
4 what Mark was looking at for the -- for the
5 logit analysis. To me, the Poisson analysis
6 would be the right analysis to be doing, and
7 he moved quickly to that.

8 Q. Why would the Poisson analysis be the right
9 analysis?

10 A. Because the Poisson is modeling counts, it's
11 not just success/failure, but it's counts.
12 One -- yeah.

13 Q. Counts of bubbles?

14 A. Counts of bubbles.

15 Q. Where?

16 A. So --

17 Q. Meaning where would the bubbles be located
18 when you're counting?

19 A. Yes. So that has to be carefully defined as
20 a point in space. And I believe what they
21 were doing, and I know what the intention
22 was, that there was a space above what might
23 be the wound or the -- the surgical site and
24 so you would count how many bubbles came into
25 that site. And I didn't pay a lot of

1 NACHTSHEIM

2 attention to the -- he had a problem with the
3 binomial logit, and I didn't think it was the
4 right way to go anyway, so he moved to the
5 Poisson and that was fine.

6 Q. Okay. And that's what was reported on?

7 A. Yes.

8 Q. Okay. Did you ever have any involvement with
9 a communication -- with any -- let me start
10 over.

11 Did you ever have any involvement
12 with any communication submitted to the FDA,
13 the Food and Drug Administration of the
14 United States, concerning any patient-warming
15 device?

16 A. I did not.

17 Q. If Mark Albrecht or Scott Augustine submitted
18 such a communication, do you believe you
19 provided any advice or consultation about the
20 substance of that?

21 A. I don't recall ever having provided any such
22 advice.

23 Q. Do you recall ever having reviewed a draft of
24 any communication prepared by anyone for
25 purposes of submission to the FDA --

1 NACHTSHEIM

2 A. I don't -- sorry.

3 Q. Go ahead.

4 A. I don't recall ever reviewing any documents
5 that were going to be submitted to the FDA.

6 Q. And I am being specific in my questions to
7 the patient -- to any patient-warming device.
8 Is that how you understood me?

9 A. Yes.

10 Q. Do you recall talking with Mark Albrecht
11 about his effort to submit a complaint letter
12 to the FDA related to forced-air warming use?

13 A. No.

14 Q. Okay. All right.

15 (Whereupon, Exhibit 17 was
16 marked for identification.)

17 BY MS. GARCIA:

18 Q. Exhibit 17 is an e-mail from Mark to you
19 attaching two draft manuscripts and some data
20 results, and a response from you to Mark
21 attaching a couple of statistical analyses;
22 is that correct?

23 A. Correct.

24 Q. And I have included everything here. I was
25 going to ask you essentially to explain your

1 NACHTSHEIM

2 comment. Your e-mail back to him says, "Some
3 new Poisson results, Box-Cox," B-O-X, C-O-X,
4 "didn't get me to normality. We should talk
5 about presentation." And I'm just wondering
6 if you can take a look at this information
7 and tell me what you meant by that.

8 A. (Reviews document.)

9 MS. GARCIA: Can we go off the
10 record for one moment.

11 THE VIDEOGRAPHER: We're going off
12 the record at 11:35 a.m.

13 (Whereupon, a brief recess
14 was taken.)

15 THE VIDEOGRAPHER: This is video
16 number 3 in the deposition of Christopher
17 Nachtsheim. Today is November 29th, 2016.
18 We're going back on the record at 11:41 a.m.

19 BY MS. GARCIA:

20 Q. Professor Nachtsheim, are you able, having
21 reviewed the materials, to explain for me
22 your comments on the bottom of the first page
23 of Exhibit 17?

24 A. Yes, I think so.

25 Q. Is it right there, (indicating)?

1 NACHTSHEIM

2 A. Thank you.

3 Q. Yes.

4 A. So I -- Mark sent -- apparently Mark sent me
5 the data, and I think there are a couple of
6 different ways of analyzing the data. One is
7 with a Poisson regression, and another is
8 with the standard sort of normal least
9 squares analysis, which is when we talk about
10 normality, that's one of the assumptions.

11 Q. Normality is an assumption?

12 A. Normality, the -- the errors are -- are
13 assumed to be normally distributed when we
14 do -- typically when we do the standard
15 regression, least squares analysis.

16 Q. Are you saying least, L-E-A-S-T --

17 A. Yes, I am.

18 Q. -- squares regression?

19 A. Yes. And so one of the things we do when we
20 run a -- if I could call that the standard
21 regression.

22 Q. Sure.

23 A. When we're on a standard regression is we
24 check that assumption, the assumption that
25 the errors are distributed normally. And if

1 NACHTSHEIM

2 they're not, we need to either do some
3 different kind of regression or we need --
4 need to make a transformation of the data to
5 try to fix that problem. And one of the best
6 ways to do that is called a Box-Cox
7 transformation, and that's -- that's what I'm
8 referring to here. And, apparently, I tried
9 a Box-Cox transformation and I said that
10 didn't get me to normality. So what I -- I
11 guess what I was concluding, I assume, was we
12 don't want to do a standard regression of
13 this data, so I guess I did some Poisson, I
14 changed the model to the Poisson model and
15 talked -- and did some analysis, which I
16 guess I've attached here.

17 Q. Okay.

18 A. Yeah.

19 Q. I have several -- thank you for that. I have
20 several questions in follow up.

21 First of all, the foundation of what
22 you said then is that the errors in the data
23 were not normally distributed?

24 A. Yes.

25 Q. What do you mean by errors?

1 NACHTSHEIM

2 A. Good question. Right. What I mean by
3 errors, when we -- when we build a model --
4 so we may -- for example, we may say -- if a
5 bubble count or model may say, well, our --
6 it models what we expect to see, let's take a
7 particular drape height and -- thinking of
8 that experiment, and one of the two modes are
9 the blankets.

10 Q. Yes.

11 A. So maybe I have the -- the Bair Hugger, and
12 two mirror high, now what -- what do we
13 expect to see in terms of number of bubble
14 counts in a particular area. And so the
15 model gives you an estimate of kind of what
16 the -- the average value should be, but the
17 data will not be exactly equal to that, it'll
18 be a little bit higher or a little bit lower.

19 Q. How does the model give you an upfront
20 evaluation of what to expect?

21 A. So when we -- when we -- well, first of all,
22 it gives us a mathematical equation. So I
23 can plug in, for example, what is the height,
24 1.5 to 0, and then I can plug in perhaps a 0
25 or a 1 --

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2 Q. For the warming unit?

3 A. -- for the warming. And I plug those right
4 into an equation. That's what I mean by a
5 model, there will be an equation. And it'll
6 then -- what comes out is the predicted
7 number of bubble -- bubble counts, but we're
8 never going to get those exactly right. It's
9 not a mathematical model, it's a statistical
10 model. And so you actually have the
11 experiment so you know what the actual counts
12 were, so you can look at what the difference
13 was between what your model said you should
14 get and what you actually got.

15 Q. Are Exhibits 4 and 5, or reference 60 on your
16 CV, which is the study that was not published
17 related to patient warming, do any of those
18 report on model predictions of bubble counts
19 or do they all report on actual observations
20 of bubble counts or is there some way those
21 two things relate?

22 A. Well, they very much relate, so the -- the
23 actual observations are input to a
24 statistical procedure which then produces the
25 model, so they're the inputs that lead --

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2 lead to the model.

3 Q. That was going to be another question I had.
4 Does the model come first or the observations
5 come first?

6 A. Observations come first.

7 Q. So you start with the observed bubble counts
8 from the experiments, you feed them into the
9 model, and then the model averages that and
10 tells you what to expect in certain
11 configurations of unit and table height?

12 A. In a sense. I mean, that's -- that's --
13 that's -- that's fairly accurate. We're
14 going to -- we're -- we have a -- we have a
15 model which is a mathematical equation, but
16 there are some constants in the model that
17 are undetermined, slopes, things of that
18 nature.

19 And when we feed the data in, the
20 statistical procedure then uses the data to
21 determine what those are. Now I have a full
22 equation and so now I actually have values in
23 my equation. The only thing that's unknown
24 in the equation are the inputs, what do you
25 want to predict for, do you want to predict

1 NACHTSHEIM

2 for the -- the -- the heat blanket or the not
3 or what height do you want to predict at, and
4 so you just put those two values into the
5 equation and out comes your prediction.

6 Q. Is the model constructed based on all
7 observations that are input initially, all
8 the observed bubble counts at all the
9 combinations?

10 A. Yes, it is.

11 Q. This model, that it -- when you say, "The
12 model," what you mean is an algorithm or an
13 equation essentially; is that right?

14 A. That's right.

15 Q. Who came up with that equation? Is it a
16 standard statistical package or is it
17 something that you or Mark wrote?

18 A. Oh, no, it's an absolutely standard
19 statistical equation and it's a standard --
20 there's a standard, if you will, formula or
21 algorithm for -- for producing that.

22 Q. Other than the observations about bubble
23 counts and parameters of table height and
24 warming-unit device, are there any other
25 parameters or assumptions you need to provide

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2 for that model?

3 A. So -- and that's one of the things I was
4 looking at. I think you're getting to one of
5 the things that I -- that I provided in -- in
6 the output at the end of this exhibit.

7 Q. Okay.

8 A. So when we have two factors, you can imagine
9 that if they -- if they are having an effect,
10 as you raise the drape from zero height to .5
11 meter height to 1 -- I can't remember what it
12 was, but from the low, medium to high height,
13 that should -- that may have an effect on how
14 many bubbles reach a particular spot, so
15 that's one effect.

16 Another effect might -- would be
17 which -- which blanket am I using. So maybe
18 one blanket leads to more bubble count,
19 more -- a higher bubble count than the other
20 blanket. So you have these two factors
21 working.

22 One of the questions we always ask
23 is -- when we begin to analyze is do they
24 work synergistically, that is, are they --
25 are these factors operating independently.

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2 And so it might be that, for
3 example, when you're -- when you're -- when
4 you're working with one blanket, the bubble
5 count goes from -- as you go up the three
6 levels, let's suppose it goes from 0 to 10 to
7 20, when you move to the other one, it
8 doesn't any longer go from 0 to 10 to 20, it
9 maybe goes from 0 to 50 to a hundred, and so
10 the level of one factor impacts the effect
11 that the other variable has, and that's
12 called an interaction.

13 So when the variables, in effect,
14 don't operate independently, there's what we
15 call an interaction. And it's very important
16 for us to figure out, when we do the
17 analysis, is there an interaction.

18 Because if -- if there is not an
19 interaction and we -- I mean, if there is an
20 interaction and we leave it out, our -- our
21 predictions are not going to be good --

22 Q. So what you --

23 A. -- the model won't be valid.

24 Q. So what you mean is then you determine if
25 you're seeing an interaction based on the

1 NACHTSHEIM

2 initial output of the model, and if you see
3 an interaction, you change the model?

4 A. Right. But usually what's done is sort of
5 the opposite direction, we usually start
6 assuming there will be an interaction and
7 then we do a -- so we fit that model and then
8 we can do a statistical test for the
9 significance of the interaction.

10 And if it's not statistically
11 significant, then we can say, ah, it's a
12 simpler situation, they operate -- these two
13 factors operate independently, we can analyze
14 them separately.

15 Q. So you began in the patient-warming work by
16 assuming there would be an interaction
17 between the warming device used and the
18 height of the drape?

19 A. Yes.

20 Q. Why?

21 A. When I say assume, I don't -- I don't -- I
22 don't say that I -- hey, I believe there's
23 going to be -- you know, scientifically I
24 believe there's going to be an interaction.
25 It's -- it's -- it's more standard

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2 statistical practice to first start with a
3 more complicated situation, a complicated
4 model, and then try to simplify it if
5 that's -- if the data permits that.

6 So -- so we start by saying -- the
7 model is the most -- the most complicated
8 version can contain -- contain the
9 interaction, so what we try to do is fit an
10 initial model with the interaction so that we
11 can answer the question is there really an
12 interaction or not.

13 Q. And you do that through a statistical test?

14 A. Exactly.

15 Q. When you fit the model to include the
16 interaction, are you telling the model which
17 warming device is likely to have what effect?

18 A. No, no.

19 Q. Here did the statistical test confirm that
20 there was an interaction or show that there
21 was not?

22 A. If I could look again.

23 Q. Sure.

24 A. (Reviews document.) This confirmed the
25 presence of interactions.

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2 Q. And could you please tell me the Bates number
3 of the document you're looking at to say
4 that?

5 A. 614.

6 Q. Okay. Is 614 the test -- does 614 and 615
7 reflect the statistical test for interaction,
8 is that all that they reflect?

9 A. They reflect the test for interaction, but
10 also the test -- also the -- asking the
11 question is the device having -- having an
12 effect on its own, so it's -- it's -- it's
13 looking at each of the components of the
14 model and asking is it statistically
15 significant, is it real.

16 Q. So then let's come back to the error
17 distribution. Does that have anything to do
18 with 614 and 615, either does it impact them
19 or is it revealed by these pages?

20 A. And you're coming back to the -- to the
21 errors where I was talking about --

22 Q. Yes.

23 A. -- the transformations and so forth?

24 Q. Yes.

25 A. Sure. So if we have -- if we -- what we're

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2 trying to do is remove all the real
3 systematic components, so if there's --
4 from -- from the data. What -- we want to
5 look at what -- what were the effects of the
6 blanket, say, and what were the effects of
7 the drape so that any differences between the
8 prediction and what we got is simply
9 experimental error, there's no systematic
10 errors.

11 For example, if I fit a model that
12 did not have interaction, did not account for
13 interaction and there really was one, then
14 our predictions are wrong and then the errors
15 are wrong, because if we don't have the right
16 predictions, we can't know what the errors
17 really are.

18 So we want to get the right model
19 and then we want to look what's leftover,
20 what we can't explain is the experimental
21 error. And how that's distributed is what's
22 key. And so I found, apparently, that it was
23 not normally distributed.

24 Q. And what does that mean?

25 A. Well, that means that if you -- so we had two

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2 times three, there were six, and we --
3 actually, that's not this experiment, but
4 let's -- this is a more complex experiment,
5 but let me keep it in that terms.

6 So we had 2 times 3 and we ran each
7 combination twice, we had 12 runs, okay? So
8 what we will do, there will be 12 errors,
9 because there's 12 observations, and they
10 will be a little bit away from what they were
11 predicted to be, each of those observations.

12 So I will have 12 errors and their
13 average will be 0, some will be positive,
14 will be too high, some will be negative, on
15 average they will be 0. And we look at the
16 distribution of those errors. Are most of
17 them small, but then we have a few large
18 ones, does it look like it follows a
19 bell-shaped distribution when we just look at
20 the errors themselves, then it follows a
21 normal distribution. And if that's not the
22 case, perhaps they're highly skewed, that's
23 not a bell-shaped curve, then we need some
24 different kind of analysis.

25 Q. Because they should be normally distributed

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2 if the model is correctly working?

3 A. That's right. We -- we -- if the model is
4 correct, then they should be normally
5 distributed.

6 Q. So when you transform the errors through one
7 of these different kinds of analysis, you're
8 changing something about the model?

9 A. Yes, I'm -- I am changing -- well, I'm
10 changing the data. So we have a lot of
11 counts, they're all positive, I might look
12 at -- for example, someone might take the
13 inverse of the numbers or the square root of
14 the numbers or the log rhythm of the numbers
15 and -- so if I -- if I take the log rhythm of
16 these numbers, and log tends to make big
17 numbers really small, so it -- it would take
18 the really big errors -- actually, I'm sorry,
19 I would take the log rhythm of the counts,
20 then I would rerun the analysis, then I would
21 get a new set of errors, and those errors may
22 follow a bell-shaped curve.

23 Q. Can you tell -- okay. So you're telling me
24 that it's standard to take the actual
25 observed data counts and transform them in an

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2 effort to get a normal distribution?

3 A. That is standard.

4 Q. Is there any type of restriction on how you
5 do that, I mean, what you can do under what
6 circumstances?

7 A. I wouldn't say there's any -- any real
8 restriction on that. That's a very standard
9 kind of procedure, as is -- and this Box-Cox
10 procedure actually looks at essentially all
11 possible transformations we could make. One
12 is a log rhythm, one might be a square root.
13 They all come under -- and it finds the
14 transformation that leads to errors that are
15 most as normally distributed as we can find.

16 Q. And you did that and you still couldn't get
17 to a normal distribution?

18 A. That's right.

19 Q. So what does that mean?

20 A. So that means that -- that means that that
21 particular fix, and it's not guaranteed, that
22 particular fix, the Box-Cox transformation,
23 was inadequate to get us where we want in
24 order to carry out the analysis.

25 Q. But why would it be? Is there anything about

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2 the underlying data, the underlying test, the
3 assumptions of the model, the appropriateness
4 of the model, these are the factors I can
5 identify, that might lead you to not be able
6 to get to a normal distribution of the
7 errors?

8 A. I think that there is often a connection
9 between how these things are distributed and
10 sort of the physics of the observation. For
11 example, we're doing counts and counts tend
12 to be Poisson -- they tend to follow a
13 Poisson distribution.

14 Q. Which is not normal?

15 A. It's not normal, it's -- it's -- it's skewed
16 to the right. Now, depending on the sample
17 size, usually or often a transformation of
18 Poisson will solve the problem. I mean, you
19 can get it back to looking like a normal
20 distribution, but that's not always
21 guaranteed.

22 Q. If that won't happen, is that an indicator
23 that your sample size may be too small?

24 A. No, no. In fact, small sample sizes
25 would -- would tend to leave you in a

1 NACHTSHEIM

2 position where you would probably conclude
3 that -- that the data are normal -- that the
4 errors are normally distributed. With
5 smaller sample sizes you tend to conclude
6 that, whether it's true or not, because you
7 don't have the power to -- to -- you don't
8 have enough data to determine is it really
9 not normally distributed, that's the way we
10 kind of approach that.

11 So, you know, my -- my approach was
12 then to say let's -- let's -- let's do the
13 Poisson regression analysis, which even going
14 into this probably would have been my bias
15 anyway, because -- because we're dealing with
16 counts.

17 Q. Okay. What is page 613?

18 A. 613 is a picture of the -- it's called a set
19 of interaction plots. So, for example, if
20 you look at -- if you look at the second
21 square in the first row where it says, "High
22 0.5," and, "Low 0.3" --

23 Q. Uh-huh.

24 A. -- that characterizes the interaction between
25 airflow and the position of the surgeon.

1 NACHTSHEIM

2 What that -- now, what is that doing. What
3 it's -- what it's -- what it's saying is that
4 when airflow is low at the .3, you notice
5 that the line is almost flat?

6 Q. Yes.

7 A. It's saying the surgeon doesn't have -- where
8 you put the surgeon doesn't have much effect
9 on counts, but the end points of that are
10 line are the first level -- you know, the
11 first -- or was it one versus two surgeons in
12 this experiment? I think it was one versus
13 two surgeons in this particular experiment,
14 not the physician, but the surgeon, we looked
15 at one or two.

16 So when there's one surgeon and you
17 move to two surgeons, there isn't much effect
18 but when the airflow is high you have a
19 steeper slope so there's a bigger difference
20 between having one surgeon and two surgeons
21 and that's why the effect of one factor
22 depends on the level of the other factor so
23 they're not independent.

24 Q. If you look at the next line, I'm sorry, it
25 says, "Two present versus absent," for

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2 surgeon, "Two present versus absent." And
3 I'm wondering, can you tell which -- there's
4 two manuscripts actually attached here.

5 A. Yeah.

6 Q. One of them has non-laminar conventional flow
7 and one of them has laminar operating room
8 ventilation. And, actually, if we look at
9 the laminar one, which is starting on page
10 577 in the, Methods, section on the second
11 page, it says that, "The experiments included
12 either an empty room or two surgeons."

13 A. Okay.

14 Q. Do you think that matches?

15 A. I think that probably matches. It's probably
16 zero versus two.

17 Q. Okay. And then I guess if we look at the
18 other one, which is conventional and
19 non-laminar flow, the second page of that
20 manuscript, which is page 557 says with --
21 "Tested with and without the presence of a
22 surgeon."

23 A. Of a surgeon.

24 Q. This conventional non-laminar flow paper, do
25 you recall ever talking about Mark Albrecht

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2 with -- about that paper at any time?

3 A. I -- I do not recall talking to him about
4 that paper.

5 Q. I think that's all I have right now on this.
6 Thank you.

7 Do you recall that using a Poisson
8 analysis worked for either one of these
9 papers?

10 A. I -- I believe it worked when I -- when I
11 gave up on the Box-Cox and then said let's do
12 the Poisson, and those are the results that I
13 provided. And one could ask did I do a test
14 of the appropriateness of the Poisson model,
15 I don't think I did that.

16 Q. How would you test for that?

17 A. That's a good question. One -- well, again,
18 one would look at -- one would look at the --
19 the distribution of the counts and one would
20 try to verify whether it, yes, is or not
21 Poisson. And the nature of the -- and,
22 anyway, I -- you know, I don't know whether I
23 did that or not, but when one has count data
24 of this type, Poisson is -- the Poisson
25 regression model is kind of the standard

1 NACHTSHEIM

2 approach to modeling it.

3 Q. If you're going to report results, should
4 somebody do the test to make sure the
5 distribution really is Poisson?

6 A. Yes, there should be some diagnostics, there
7 should be some looking at do the residuals
8 that result have the right -- have the right
9 distribution.

10 Q. Do you know if that was ever done?

11 A. I don't -- on this paper it doesn't look like
12 it was done.

13 Q. Okay.

14 A. I don't see -- at least I don't see any
15 reports of that.

16 Q. When you say, "On this paper," are you
17 referring to both of the abstracts --

18 A. No, no.

19 Q. -- included in this exhibit --

20 A. No, I'm sorry, I was referring to the -- to
21 the one that I was involved in.

22 Q. The two versus zero?

23 A. Yes.

24 Q. Did the two versus zero become either Belani
25 or McGovern or the exhibit -- or, I'm sorry,

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2 item 60 on your CV?

3 A. No.

4 Q. No?

5 A. No.

6 Q. If you wouldn't mind reassembling Exhibit 17
7 with the e-mail on top, that would be great.

8 A. I'm --

9 Q. I think if the documents go in Bates number
10 order it'll be perfect.

11 A. 556, 577 -- these are -- I'm sorry -- 548, is
12 this all one? Yes.

13 Q. I think you might have -- that goes -- yeah.
14 Oh, I think, actually, that's okay.

15 A. 548, 556, this would be 600.

16 Q. Okay.

17 A. And then I believe this was --

18 Q. Perfect. Thank you.

19 A. -- at the end, right? And it's --

20 Q. Yes.

21 A. -- 613, 614.

22 Q. Thank you.

23 A. Not one of my skills.

24 Q. Well, you did it.

25 If you would take a look at

1 NACHTSHEIM

2 Exhibits 4 and 5, please, and see if you're
3 able to determine if what type of modeling --
4 well, okay. So if we look at Exhibit 4,
5 which is McGovern, on the bottom of page
6 1540, Statistical Analysis. I'll wait for
7 you to get there. Bottom of page 1540.

8 A. Oh, yeah, this is --

9 Q. No, you have the right one in front of you,
10 Exhibit 4, McGovern.

11 A. Okay. Oh, yeah, got it. All right.

12 Q. It says, "A Poisson regression model was
13 fitted to the hip replacement data having the
14 sum of bubble counts for each experimental
15 run, five photographs as the response, and
16 the factors identified in the experimental
17 design as predictors." Is that consistent
18 with the description you just gave about a
19 model?

20 A. Yes, it is.

21 Q. And it says, "Differences in demographics and
22 comorbidities between the patient-warming
23 groups were assessed by analysis of variance,
24 ANOVA, or log-linear contingency table
25 methods." What does that mean?

1 NACHTSHEIM

2 A. Okay. So if -- right, this has -- can you
3 tell me where it says that? I just want to
4 be sure I'm --

5 Q. Yes, on page 1540, top of the right column.

6 A. Top of the right column. Okay. Good.

7 Q. Just that one sentence.

8 A. Uh-huh. So what we're trying to determine
9 there, are there -- are there differences in
10 the -- in the -- and I believe this has to
11 do -- I want to be sure about this. This has
12 to do with the hospital data.

13 Q. Okay. Then I want to hold it. I want to
14 hold that for later. Thank you.

15 A. Okay.

16 Q. So for the statistical analysis going back to
17 the Poisson regression model, that has to do
18 with the bubble counts?

19 A. Correct.

20 Q. Can you determine from the statement in this
21 paper whether the distribution was tested to
22 see if it really was Poisson?

23 A. I can't determine that. Yeah, I -- I don't
24 believe that was reported.

25 Q. Do you have any belief about whether it was

1 NACHTSHEIM

2 done?

3 A. I really -- I don't know and I don't
4 recall -- I don't recall seeing -- I don't
5 recall seeing it done.

6 Q. What would it mean if the distribution were
7 tested and it was not really a Poisson
8 distribution, but you used a Poisson model?

9 A. That could mean that there would be some --
10 some bias, for example, in the p-values, the
11 statistical significance levels reported,
12 they might not be -- they might not be as
13 accurate. They may not be accurate.

14 Q. Does it tend to bias them high or low?

15 A. I -- I think that really depends on the
16 nature of the -- the real distribution.

17 Q. Okay. So you could get a statistically
18 significant difference when, in fact, there
19 isn't one if you've used a Poisson model and
20 the distribution of bubbles is actually not
21 fitting a Poisson distribution?

22 A. That's possible.

23 Q. If we would look at Exhibit 5, which is the
24 Belani paper, on page 408, Statistical
25 Analysis --

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2 A. Yup. Yes.

3 Q. -- the first sentence is, "A Poisson
4 regression model for overdispersed data was
5 fit having the sum of bubble counts for each
6 experimental run, ten pictures as the
7 response and the factors identified in the
8 experimental design as predictors, plus an
9 interaction term." What does that tell you?

10 A. So we counted the -- there was a series of
11 pictures taken over time, they added up all
12 the bubbles in all the pictures to get a
13 response, and so those are the responses --
14 responses that were being modeled. A Poisson
15 regression model was used.

16 Again, it's -- it's standard to use
17 a Poisson regression model for count data.
18 And often, probably more often than not, the
19 Poisson model -- there's an interesting thing
20 about the Poisson model, that the variance of
21 the errors, how big -- how big those errors
22 are around the point you're -- you're
23 estimating are -- is actually equal to the --
24 to the actual value that you're -- your
25 prediction.

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2 So the mean at a -- at a particular
3 combination of factors, you know, drape
4 height and what -- what blanket you're using,
5 the mean and the variance -- the mean,
6 meaning the prediction value, and then the
7 variance around that are the same.

8 Q. Okay.

9 A. That's a -- that's a consequence of the
10 Poisson -- Poisson distribution.

11 Q. Is that overdispersion?

12 A. When that's not true --

13 Q. Okay.

14 A. -- when -- and often -- in fact, it's almost
15 standard that -- that that variance is
16 actually larger than it would be under a pure
17 Poisson model. And if that's the case, then
18 we use what's called an overdispersed model
19 and -- and we want to -- basically, what
20 we're saying is that the variance -- if we
21 just used a pure -- pure Poisson model, the
22 variance of the errors would be too small.
23 That has the effect of making things
24 statistically significant.

25 Q. When they aren't?

1 NACHTSHEIM

2 A. When they aren't.

3 Q. Okay.

4 A. So a smaller variance can tend to make things
5 more statistically significant. So these --
6 it can magnify the effects, and that would be
7 a bias.

8 So in this case we saw some evidence
9 of overdispersion and so we used what's
10 called the overdispersed model, and that
11 allows the variance to be larger than that
12 mean. We kind of use the data to determine
13 how large that variance should be and
14 hopefully remove any bias that you might have
15 in terms of the statistical tests.

16 Q. Can you determine from the write-up of the
17 statistical analysis in Exhibit 5 if the
18 testing was done that you earlier described
19 to determine if there really was a Poisson
20 distribution in the bubble counts?

21 A. I -- I -- I don't -- I don't see that.

22 Q. Do you have any knowledge of whether that was
23 done for the Belani study?

24 A. I don't.

25 Q. If --

1 NACHTSHEIM

2 A. I don't.

3 Q. -- you had -- if the -- let me start over. I
4 apologize.

5 If anyone had done the testing to
6 determine if there really was a Poisson
7 distribution, would it be standard to report
8 that in a peer reviewed article?

9 A. It would be standard. And, in fact -- and,
10 in fact, if you found that things were not
11 following a Poisson distribution, then we
12 would need to resort to transformations or
13 some other kind of approach, some other model
14 that would -- that would try to better
15 reflect the nature of the errors.

16 Q. You should do that if you had determined that
17 there wasn't a Poisson distribution?

18 A. That's right. That's right.

19 Q. But in terms of what if you determined that
20 there either -- let me -- if you determined
21 that there was a Poisson distribution, would
22 that normally be reported in a peer reviewed
23 paper?

24 A. Not -- I don't think so, in the sense that --
25 and I'm not saying it shouldn't be. I'm just

1 NACHTSHEIM

2 saying I don't think it's standard practice
3 to go that deep when we're dealing with
4 counts, Poisson, when you're dealing with
5 success/failure logistic. I mean, it's kind
6 of the way -- the way -- those are sort of
7 standard operating procedures.

8 Q. So a peer review -- a peer reviewer or a
9 knowledgeable person reading the paper would
10 not find it surprising to have a Poisson
11 analysis for the counts?

12 A. Right.

13 Q. But behind the scenes, the person actually
14 conducting the study still should be testing
15 the distribution to be sure that it is
16 Poisson or you're --

17 A. I think it's --

18 Q. -- using a Poisson model?

19 A. Yes. There are various diagnostic things one
20 looks at and looks for outliers and things of
21 that nature.

22 Q. Is there a standard name of that test that
23 you're talking about or those tests?

24 A. Well, these are -- there's a family of tests
25 for -- for goodness of fit, called goodness

1 NACHTSHEIM

2 of fit tests.

3 Q. Okay. Is that the term by which they would
4 normally be?

5 A. I think so.

6 Q. Goodness of fit test. Okay. Thank you for
7 all of that statistics.

8 A. That's my favorite part.

9 Q. I know. Or I -- I -- I'm gathering, I should
10 say, not I know. That was imprecise of me.

11 I just want to show you this and see
12 if you have any memory of it.

13 (Whereupon, Exhibit 18 was
14 marked for identification.)

15 BY MS. GARCIA:

16 Q. So for -- Exhibit 18 is an e-mail from Mark
17 to you referring a warning letter to Arizant.
18 And it says, "Whoa, didn't expect to see that
19 they are already in trouble for past
20 offenses." Do you recall talking with Mark
21 about this?

22 A. No.

23 Q. Do you recall reading it?

24 A. I do recall reading it.

25 Q. And do you have any -- did you have any

1 NACHTSHEIM

2 context for it, any understanding about it
3 beyond the words?

4 A. No. No, I read it -- I read it with
5 interest. There was the link provided down
6 below and the report from the FDA, as I
7 recall. I just read it. I -- I didn't have
8 any comment on it, I just -- I thought it was
9 interesting.

10 Q. You don't have any knowledge about what led
11 to it or --

12 A. I did -- I did not.

13 Q. Okay.

14 A. There -- there appeared to be some slaps on
15 the wrist or some difficulties. I -- you
16 know, I just read it and, oh, that's
17 interesting.

18 Q. Whatever you knew about it was in the context
19 of the warning letter -- in the content of
20 the warning letter itself?

21 A. Exactly. I knew nothing else about it.

22 Q. Okay. Let me just take a second while we sit
23 here and look at my notes to see -- sorry,
24 I'm just looking for some paper in the midst
25 of paper.

1 NACHTSHEIM

2 MR. SACCHET: Do you want to take
3 a lunch break or something?

4 MS. GARCIA: Well, yeah, but I was
5 just -- we will take a lunch break, thank you
6 for asking, but I just wanted to do a few
7 things if people are okay to go a little bit
8 longer. But I'm looking for an outline and
9 I'm not finding it. If I don't find it
10 soon -- it must be in front of me. My
11 goodness. I know I had it this morning.
12 I've seen it since we've been sitting in this
13 room, so this is not a goose chase. All
14 right. Well, shoot. Oh, there it is. Thank
15 you. Okay.

16 BY MS. GARCIA:

17 Q. So if we would look at, please, Exhibit 4,
18 which is the McGovern study we've been
19 spending so much time with today. Do you
20 have any belief that you spoke with
21 Mark Albrecht about that study before he sent
22 you a draft manuscript?

23 A. I don't recall that -- before I saw a draft
24 manuscript that I had seen any -- any of
25 this.

1 NACHTSHEIM

2 Q. Do you recall any participation in the design
3 of the study before the bubble experiments
4 were conducted?

5 A. No, only inasmuch as we -- we may have talked
6 about the design in the sense that there's --
7 it's a simpler experiment going to be
8 performed than the previous work we had done.
9 It was just a couple of factors and so forth,
10 but -- so I had -- until I saw a draft of
11 this, pretty much, no, I'll say no.

12 Q. Involvement in it?

13 A. No involvement.

14 Q. Okay. With respect to the -- we've talked a
15 lot about bubble counts here today. But as
16 you noted -- as you noted earlier, the
17 McGovern paper also includes reference to
18 infection data from a -- from someplace, from
19 one or more hospitals. Do you know the
20 source of the infection data?

21 A. My -- my understanding it was -- it was one
22 hospital and it was one of the hospitals
23 where one of the physicians worked.

24 Q. Who was an author on the paper, do you mean?

25 A. I think so. That's what I thought.

1 NACHTSHEIM

2 Q. Did you have any contribution to the design
3 of that portion of the study?

4 A. No.

5 Q. Either before or after you saw an abstract --
6 I mean, I'm sorry, either before or after you
7 saw a draft manuscript?

8 A. And you're really talking about the -- the
9 infection data?

10 Q. Yes.

11 A. I -- and -- and so I tend to -- I tend to not
12 think of it as a design study. I tend to
13 think of it as an observational study just --
14 we're just collecting data through time, so
15 I -- I just -- I'm making a small point.

16 Q. No, that's -- thank you for clarifying that.

17 A. And I -- I didn't have -- but I had no input
18 when they were starting collecting data and
19 when they were going to end, any of that.

20 Q. The phrase you're using and the motion of
21 your hands would indicate a forward-looking
22 study, but was this prospective or
23 retrospective data collection?

24 A. So my understanding was that part of this
25 data had -- was already in the records when

1 NACHTSHEIM

2 they decided to start collecting this data
3 and that -- so they had been using forced
4 air, they went through a transition and then
5 they started using conductive fabric.

6 And the first time I saw the data,
7 there actually had not been any -- any
8 infections, it was a time period following
9 this -- this -- this time and there
10 weren't -- the actual number of infections
11 was zero when one of the manuscripts was
12 completed.

13 But the study continued on for
14 another period of time, I don't know, for
15 another year, and then -- and then there were
16 some infections that showed up so the
17 analysis was redone.

18 Q. So first of all, to be clear, you're
19 referring to page 1543 in the McGovern
20 article, right?

21 A. Yes.

22 Q. And the figure there shows a couple of
23 vertical lines to mark the beginning and end
24 of a transition period -- of a labeled
25 transition period, correct?

1 NACHTSHEIM

2 A. Correct.

3 Q. And when you were originally saying that
4 there was a time frame when there was zero
5 infections, you were referring to a time when
6 the conductive fabric was being used?

7 A. I'm sorry, that's exactly what I meant.

8 Q. No need to apologize. I just want to make
9 sure the record is clear for -- for -- for
10 folks who aren't looking at the picture, the
11 graphic.

12 Do you understand which -- whether
13 forced air or conductive fabric is the
14 Bair Hugger device?

15 A. Well, my understanding was it was the
16 Bair Hugger device.

17 Q. Do you understand what device was used as a
18 conductive fabric device?

19 A. No, I don't, actually. I think I made an
20 assumption that it was this HotDog.

21 Q. Well, and it might say so right in the --

22 A. It might say so.

23 Q. -- right in the study. In fact, I -- I sure
24 believe it might. If we take a look at --

25 MR. SACCHET: 1538.

1 NACHTSHEIM

2 MS. GARCIA: 1538.

3 MR. SACCHET: Right-hand side
4 about halfway down.

5 MS. GARCIA: "The upper body
6 warming treatment was introduced under the
7 drape," well, that's the bubble count. Thank
8 you. I'm looking for the infection data.
9 (Reviews document.)

10 BY MS. GARCIA:

11 Q. I'm not seeing the word HotDog yet. Do you
12 believe that the infection data reflects the
13 use of a HotDog as the conductive fabric
14 blanket or do you have any belief about that
15 at all?

16 A. I don't have any belief about it at all,
17 unless I can find it documented in the paper.
18 I mean -- so I don't -- and I haven't found
19 it, so I have no belief about what kind of
20 forced-air warming we're using. I just
21 always assumed this was going to be the
22 Hot -- the Bair Hugger.

23 Q. And --

24 A. It doesn't -- if it doesn't say that, I don't
25 know.

1 NACHTSHEIM

2 Q. And you do know that the Augustine company
3 makes and sells or sells the HotDog
4 patient-warming device?

5 A. I do.

6 Q. And you knew that at the time that you worked
7 on this?

8 A. I did.

9 Q. And you know that the HotDog warming device
10 is in competition with the Bair Hugger
11 warming device?

12 A. Yes.

13 Q. You said something about the study continued
14 for a year. But if I look at the conductive
15 fabric timeline back on page 1543, the entire
16 time period during conductive fabric is only
17 July 2010 to January 2011; is that right?

18 A. Yes, and I misread that.

19 Q. So what's the -- what is the length of that
20 entire time frame?

21 A. So it looks like it's -- I don't know the
22 exact number. It looks like it's a little
23 bit over -- it would be a little bit over six
24 months, correct?

25 Q. That's how I would read it.

1 NACHTSHEIM

2 A. Yeah, yeah. My mistake.

3 Q. And what is the length of the time frame
4 attributed to forced-air warming?

5 A. So it looks like it started around July 2008
6 and ended in January 20 -- a little after
7 January 20 -- maybe a month or two after
8 January 2010, so it looks like three --
9 three-plus -- or I'm sorry, two-plus years.

10 Oh, no, no, no, no, no. Let's see.
11 No, I see how they're doing it, one and a
12 half -- it's over one-and-a-half years,
13 right? So July 2008 until perhaps March of
14 2010.

15 Q. There were -- there was statistical
16 comparison made between the infections
17 observed and recorded during the time when
18 the forced-air warming was used and during
19 the transition time and during -- let me take
20 that question back.

21 You said earlier that you don't
22 think of an observational study having a
23 design, and I'm kind of confused by that.

24 An observational study certainly has
25 some constructs or frameworks under which

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2 it's being conducted, right?

3 A. Well, it depends on the observational study.

4 Sure, that's true. I mean, we have
5 prospective and retrospective and -- and so
6 forth, and that implies a lot of design.

7 There's also simply analysis of historical
8 data, which I don't think -- which I don't
9 tend to think of as being designed.

10 The only -- you know, I think the
11 only thing that matters here is when did
12 the -- when did these -- the only design part
13 of this is how long -- I suppose how long did
14 it go on, when did it start and when were the
15 transitions and when did it end.

16 And I don't know -- I don't know
17 that the transition points were -- were --
18 I'm not aware that the transition points were
19 dictated by our study. I -- I always
20 assumed, and this may be just a bad
21 assumption, that this was something that came
22 from the hospital administration and it was a
23 convenient -- you know, in a way, it's a
24 pseudo experiment, because you're changing
25 something and you can see does it change in

1 NACHTSHEIM

2 time, do things change along with it.

3 So I'm being a little pedantic here,
4 but I'm not sure -- I don't know who made the
5 decisions about when it starts, when it ends
6 and when those transition points were to
7 occur.

8 Q. Is prospectively collected data generally
9 considered to be of higher value and to offer
10 a study more strength and validity than
11 retrospectively-collected data?

12 A. I think it has some strengths that
13 retrospective data does not have.

14 Q. Can you explain that for me, please.

15 A. Well, so in a prospective study we're going
16 to -- we may take a group of people and move
17 forward in time, we may monitor how they
18 behave, we may monitor the incidence of
19 diseases and so forth, right?

20 And so is -- and we may even --
21 let's see, why am I blanking on this. When
22 we go back in time we, in a sense, have to
23 pick people to observe and then we have to
24 then look at -- look at their records and go
25 forward with it. So I think there's an added

1 NACHTSHEIM

2 complication going back in time about who do
3 you pick and when do you start and so forth.

4 Q. And whether you can even identify those
5 people who would otherwise be included in
6 your data set?

7 A. Yes.

8 Q. So looking backward in time, there may be,
9 for example, some people who had hip and knee
10 surgery who aren't included in the data set
11 because the way the hospital records were
12 being kept and the way the data set is being
13 selected you just can't match them up?

14 A. You can't go back and control for that.

15 Q. If you were going forward saying I'm going to
16 look at all hip and knee surgeries, you could
17 more carefully make sure you get them all?

18 A. I agree, yes.

19 Q. If it were important to you to know about
20 certain risk factors that people have that
21 could influence their chances of getting an
22 infection, that's also something you could
23 make sure you're carefully recording?

24 A. Yes.

25 Q. And you could make sure that you're recording

1 NACHTSHEIM

2 that in a more specifically defined way so
3 that you're comparing like to like?

4 A. Yes.

5 Q. When you look retrospectively, you may find
6 that that data wasn't recorded --

7 A. Wasn't -- I'm sorry. Yes, you may find it
8 was not recorded.

9 Q. Or that it wasn't recorded in a uniform way?

10 A. Correct.

11 Q. Why is it important in an observational study
12 to account for factors that may predispose a
13 person to infection risk if what you're
14 looking at is infection risk?

15 A. So the -- the concern could be in -- in a
16 study like this, to make -- to make this
17 very, very simple, suppose that -- suppose
18 that as you look -- as you looked back --
19 because I think this is -- I think this is
20 kind of both, I think there was some lookback
21 and then I think there was some going forward
22 involved in this study.

23 Q. In the McGovern study?

24 A. Yeah, in the McGovern study. So we would --
25 we would like to think that the subjects

1 NACHTSHEIM

2 involved going forward were not different
3 than the subjects involved -- going backward
4 and going forward are the same, so that
5 these -- so that any difference -- you would
6 like to -- you would like for them to be
7 essentially homogeneous so that any
8 differences you see, you can ascribe to what
9 you know changed in this case, the -- the
10 conductive fabric, but you can't control that
11 and there -- there -- there -- so there could
12 be other changes going on that you're not
13 taking into account, you know. And I made a
14 bad example saying maybe the people before
15 the change were -- were older and we suddenly
16 had a lot of younger people in the next --
17 and so maybe the older people were more
18 likely to get infection. So you'd like to
19 believe that the two groups are homogeneous
20 and the only difference is the -- is the
21 fabric in this case, is the treatment, but
22 this is not a randomized experiment, so you
23 can't absolutely -- you can't -- you can't --
24 you don't have the same power, you don't have
25 the same ability to ascribe cause and effect

1 NACHTSHEIM

2 as you would if you had run an experiment.

3 Q. Okay. And --

4 A. That's the main -- when I say observational
5 study versus experimental study, we really
6 have the ability when we run experiments to
7 be sure that essentially the only difference
8 between the treatment groups is the
9 treatment. We don't have that power
10 necessarily in an observational study.

11 Q. So would that be, for example, why, looking
12 at page 1543 of the McGovern paper, in the
13 left-hand column, the first full paragraph
14 says, "This study does not establish a causal
15 basis for this association. Although the
16 demographics were similar between the patient
17 and groups in terms of risk factors for
18 infection, the data are observational and may
19 be confounded by other infection control
20 measures instituted by the hospital," would
21 that be one -- one reason behind that --

22 A. Exactly.

23 Q. Okay. Did you read this limitation -- or,
24 I'm sorry, did you read this language in the
25 abstract -- let me start way over.

1 NACHTSHEIM

2 Did you read this portion of the
3 paper before it was submitted for
4 publication?

5 A. Yes, I did.

6 Q. And do you agree that the McGovern paper by
7 itself could not establish -- or let me start
8 over.

9 Do you agree that the McGovern paper
10 by itself does not establish a causal
11 relationship between the selection of
12 patient-warming device and infection risk?

13 A. I believe that.

14 Q. Do you believe that the McGovern paper, taken
15 together with the other papers cited within
16 it, collectively do not establish a causal
17 association between or a causal effect
18 between selection of warming device and
19 infection risk?

20 MR. SACCHET: Objection;
21 foundation.

22 THE WITNESS: I don't believe that
23 a causal basis has been established.

24 BY MS. GARCIA:

25 Q. Are you aware of any randomized clinical

1 NACHTSHEIM

2 trial that has been controlled that has
3 demonstrated an increased infection risk when
4 the Bair Hugger device is used as opposed to
5 a different kind of warming device?

6 A. No, I'm not aware of any such study.

7 Q. Are you aware of any study showing any type
8 of forced-air warming device causes an
9 increase in infection risk as compared to a
10 device that doesn't use forced-air warming?

11 A. Again, I'm not aware of any such study and
12 I -- yeah.

13 Q. Why would it be important in an observational
14 study -- well, you've mentioned why,
15 actually, it would be important in an
16 observational study to -- let me start that
17 over again too. I apologize.

18 There are some tools available in
19 observational studies to try to account for
20 underlying differences in people or in
21 circumstances if you had the data available;
22 is that right?

23 A. Yes.

24 Q. Is multivariate regression analysis one of
25 those tools?

1 NACHTSHEIM

2 A. Yes.

3 Q. Did you ever discuss with Mark Albrecht or
4 anyone else the possibility that multivariate
5 analysis be used on the infection data in the
6 McGovern paper?

7 A. I did not. There are -- because -- well,
8 there are a couple of approaches that can be
9 used, and I think one is a multivariate
10 regression approach.

11 Another thing that's done in a case
12 like this often is simply going back and --
13 and comparing characteristics of the subjects
14 in the two groups and looking for -- for
15 differences that might explain the results,
16 and that's very much related to what
17 multivariate regression would do.

18 So if there are differences -- in
19 the multivariate regression, if there really
20 were differences, one could adjust for those.

21 Q. Statistically?

22 A. Statistically, and still maybe able to answer
23 the question were there differences in
24 infection rates that are -- that go beyond
25 the differences in -- in demographic factors.

1 NACHTSHEIM

2 Q. But that wasn't done here for the McGovern
3 paper?

4 A. That wasn't done. And I think the reason was
5 that looking at -- that they didn't find
6 differences in the demographic factors that
7 they had.

8 Q. Are you saying that based on the statement we
9 just read in the article?

10 A. No, I'm saying it on the basis of the -- of
11 the -- of the -- the ANOVAs and -- and -- and
12 the sort of comparisons that were doing
13 between the -- between the groups.

14 Q. Okay. Can you show me what you're referring
15 to?

16 A. Okay.

17 Q. I think by the fact that you're turning the
18 page, you mean something within this article?

19 A. I think it's this article. I hope -- yeah.
20 Yes, it's this article.

21 Q. Page 1540, is that what you mean?

22 A. I think so. (Reviews document.)

23 Q. I believe it's page 1540.

24 A. So one of the -- one of the statements is,
25 "The demographics of 1,437 patients

1 NACHTSHEIM

2 undergoing hip or knee replacement revealed
3 no significant difference between the two
4 types of warming for SSI risk factors of age,
5 type of surgery, diabetes, length of
6 preoperative stay," referring to table 1.

7 Q. Okay. You've read that from page 1541?

8 A. I did.

9 Q. Do you have any understanding about what are
10 the significant risk factors that would
11 influence infection risk in a person
12 undergoing hip and knee surgery?

13 A. No.

14 Q. Are you able to judge whether this list
15 captures the important risk factors one would
16 care about if one wanted to determine if the
17 patients in one group versus another really
18 were similarly situated as to infection risk?

19 A. No.

20 Q. Did you ever ask anyone about that to say to
21 Mark Albrecht or anyone else, Are we
22 accounting here for the significant risk
23 factors that people might bring into the
24 operating room?

25 A. No.

1 NACHTSHEIM

2 Q. And if you look at the next sentence, it
3 says, "Unfortunately record-keeper" --
4 "recordkeeping was incomplete for the
5 additional risk factors of blood transfusion,
6 obesity, incontinence and fitness for surgery
7 which have been identified elsewhere as
8 important predictors for deep infection"; is
9 that correct?

10 A. That's correct.

11 Q. And if they are important predictors for deep
12 infection, those are things you would ideally
13 like to be able to adjust for or evaluate if
14 you're comparing the groups?

15 A. You'd like to -- right, you'd like to
16 evaluate, and if there really was a
17 difference, then you'd want to adjust for it.

18 Q. Are you saying that -- and that is because if
19 people are different on those factors, they
20 might bring a different infection risk into
21 the operating room, which could account for
22 differences in observation?

23 A. Correct.

24 Q. Are you saying that if you just look at the
25 absolute count and percentage of people who

1 NACHTSHEIM

2 have these different risk factors between the
3 two groups and they look similar, you would
4 not do a multivariate analysis, there
5 wouldn't need to be a multivariate analysis?

6 A. Correct.

7 Q. Would you do any type of statistical testing
8 to see if those observed differences were
9 statistically similar to each other -- I'm
10 sorry, if the observed conditions were
11 statistically similar to each other?

12 A. I would certainly want to do the -- the
13 analysis to see for every -- all the people
14 we have in these groups, are we seeing
15 systematic differences.

16 Q. And how would you do that?

17 A. Well, the methods are two-sample T-test,
18 two-sample proportion, tests of proportion,
19 are the proportions different, the proportion
20 that have, for example, diabetes, is that --
21 is that -- is that statistically different in
22 the groups or not, so those kinds of
23 questions.

24 Q. Do you know if any of that work was done?

25 A. That work was done for these variables.

1 NACHTSHEIM

2 Q. And how do you know that?

3 A. Well, it -- the -- it's -- it's reported
4 here. Well, it said that the demographics --
5 again, the sentence that I read previously.

6 Q. It refers to table 1. If you look at
7 table 1 --

8 A. Right.

9 Q. -- does that tell you?

10 A. Right. Right. Yes. Oh, as a matter of
11 fact, it does. So the p-values -- right. So
12 there's a T-test done for the difference in
13 age in years and the p-value was .867, which
14 indicated no difference. And then down below
15 there were tests of proportions and the
16 p-values of .261, .976, .240 indicated no --
17 and .075 indicated no statistically
18 significant difference.

19 Q. So for the mean age in years, for the number
20 of procedures, for diabetes and for the
21 duration of preoperative hospital stay zero
22 or greater than one days, tests were done to
23 show that the groups were statistically
24 similar to each other?

25 A. Correct.

1 NACHTSHEIM

2 Q. Are you aware of any other factors on which
3 the groups were compared?

4 A. I am not aware of any other factors.

5 Q. Would you expect, if there were other factors
6 that they were able to compare the groups on,
7 that would have been included in the
8 published paper?

9 A. Absolutely.

10 Q. And then if you turn back to page 1540 where
11 we were looking before, at the top of the
12 right column, it says, "Differences in
13 demographics and comorbidities were assessed
14 by analysis of variance ANOVA or log linear
15 contingency table methods and univariate odds
16 ratios for the development of joint substance
17 were computed."

18 Is this something that's reported in
19 the paper, the data from those analyses?

20 A. Can you show me where you're -- I'm sorry.

21 Q. Yeah. Right underneath this bar graph, the
22 top right paragraph.

23 A. Sorry, what -- what -- I'm on the wrong page.

24 Q. 1540.

25 A. 1540?

1 NACHTSHEIM

2 Q. Flip it the other -- flip your --

3 A. Oh, the other way.

4 Q. Just take your stack and flip it.

5 A. 1540. I went the wrong way. Got it. Okay.

6 And it's right in that -- underneath that.

7 Q. Top right paragraph.

8 A. Got it.

9 Q. Are the results of this univariate analysis
10 reported somewhere in this paper?

11 A. I believe that refers to that -- to the table
12 we were just talking about in table 1.

13 Q. And then I guess if we look at table 2?

14 A. And then table 2 -- okay. And so then
15 they're breaking it down.

16 Q. And if we would look at --

17 A. So table 2 is looking at the differences, I
18 guess -- hold on. (Reviews document.)
19 Differences in people who developed
20 infections versus did not develop infections.

21 Q. The --

22 A. But it --

23 Q. The odds ratio for developing an infection
24 was much higher in a hip surgery than in --
25 the -- the -- I'm sorry.

1 NACHTSHEIM

2 The observed risk for developing
3 infection was four times higher in a hip
4 surgery than a knee surgery, correct?

5 A. Yes.

6 Q. And that was statistically significant, that
7 difference?

8 A. Yes. The p-value was less than .001, I
9 guess.

10 MS. GARCIA: I would like to
11 propose that we go ahead and -- actually,
12 before I -- before I break for lunch, I just
13 want to make sure I understand. I've gone so
14 many different places. I'm going to come
15 back and have some more questions about this
16 study.

17 BY MS. GARCIA:

18 Q. But the statistical analysis that was
19 conducted on these infection data that's
20 ultimately reflected in the McGovern paper,
21 do you recall having any conversations with
22 Mark Albrecht about that analysis before he
23 did it?

24 A. There are sort of three different -- I mean,
25 there's sort of three different analyses, one

1 NACHTSHEIM

2 has got to do with the experiment itself.

3 Q. I mean the infection data.

4 A. The infection data. I -- I did not consult
5 with him regarding the -- you know, the kind
6 of -- the kind of before and after
7 demographic kind of thing that we've been
8 looking at, I did not talk to him about that.
9 I talked to him a bit about how to do this
10 analysis, the analysis of the -- providing
11 the confidence intervals and so forth that
12 are shown in Figure 7.

13 Q. And I do believe, and we can look at those
14 after lunch, I do believe there were a couple
15 of e-mails about that, and my recollection is
16 he presented the data to you that's reflected
17 in Figure 7, the graphic, and you suggested
18 that he added confidence intervals; does that
19 sound right?

20 A. Yes.

21 Q. So did you discuss the analysis he did before
22 he did it?

23 A. And by, "Analysis," do we mean adding the
24 confidence intervals or simply -- because the
25 analysis is basically here, it's basically

1 NACHTSHEIM

2 computing the -- the infection rates for the
3 three areas, the infection rate for sort of
4 before transition --

5 Q. Right.

6 A. -- and after. I didn't talk with him about
7 that before I saw the original sort of
8 analysis that did not have confidence
9 intervals on it.

10 Q. And the choice to do univariate or
11 multivariate regression analysis, did you
12 speak with him about that at any time?

13 A. Did not. I did not.

14 Q. Okay. The decisions about which factors to
15 evaluate that might predispose a person to
16 infection risk, did you have any input into
17 that decision?

18 A. I did not.

19 Q. The decision about where to draw the lines in
20 the period where forced-air warming
21 transition and conductive warming, you --

22 A. No, I --

23 Q. -- did not have --

24 A. No.

25 Q. -- any involvement in those -- any discussion

1 NACHTSHEIM

2 about that?

3 A. I had no involvement, there was no
4 discussion. This was just -- the data were
5 presented to me, Here it is, you know, this
6 is the transition period and here's before
7 and after.

8 Q. Other than suggesting to Mark Albrecht that
9 he add the confidence intervals to results
10 that are presented on Figure 7, do you recall
11 providing Mark with any input or guidance or
12 suggestion about either the design or the
13 statistical work that's reflected in
14 Exhibit 4 with respect to infection data?

15 A. No.

16 Q. And I just cannot recall, so please remind me
17 if you recall having given him any input or
18 guidance or advice about the design or
19 analysis reflected in the bubble count data
20 in Exhibit 4?

21 A. I'm sorry, is the question -- could you
22 repeat the question for me?

23 (Whereupon, the last question
24 was read by the court reporter.)

25 THE WITNESS: So originally -- oh,

1 NACHTSHEIM

2 in Exhibit 4.

3 MS. GARCIA: The McGovern paper.

4 THE WITNESS: Oh, the McGovern
5 paper. This is the McGovern paper, right?
6 So exhibit -- I was looking at Figure 7.
7 Exhibit 4, I'm sorry. That's why I didn't
8 understand.

9 I may have -- may have urged him to
10 add the confidence intervals to -- oh, that's
11 Figure 5. Figure 4, no. Sorry. You finally
12 got me to Figure 4. No, I did not have any
13 input into that figure.

14 MR. SACCHET: I just want to be
15 clear, are we talking about Figure 4 or
16 Exhibit 4?

17 MS. GARCIA: Both.

18 MR. SACCHET: Okay.

19 MS. GARCIA: I believe.

20 BY MS. GARCIA:

21 Q. Is that correct?

22 A. Yeah, they're --

23 Q. Figure 4 of Exhibit 4?

24 MR. SACCHET: That's what you were
25 asking or just bubble count --

1 NACHTSHEIM

2 THE WITNESS: Let's be absolutely
3 sure here.

4 MS. GARCIA: Yeah, let's be
5 absolutely sure.

6 THE WITNESS: Exhibit 4, Figure 4
7 I did not have any input to -- I don't recall
8 having input to that figure.

9 MS. GARCIA: Okay.

10 BY MS. GARCIA:

11 Q. I think my question -- what about Exhibit 4,
12 Figure 5?

13 A. I may have urged him to add the confidence
14 intervals to the -- to the bars, but I can't
15 say for sure.

16 Q. Okay. Other than that possibility, do you
17 believe that you provided any insight or
18 guidance to Mark Albrecht or anyone else
19 about any aspect of the bubble count
20 experiments and their analysis that is
21 reported in Exhibit 4, the McGovern article?

22 A. I don't believe so.

23 MS. GARCIA: Why don't we break
24 and I will come back organized after the
25 break with some more questions.

1 NACHTSHEIM

2 THE VIDEOGRAPHER: We're going off
3 the record at 12:57 p.m.

4 (Whereupon, a lunch recess
5 was taken.)

6 THE VIDEOGRAPHER: This is video
7 number 4 in the deposition of Christopher
8 Nachtsheim. Today is November 29th, 2016.
9 We're going back on the record at 1:54 p.m.

10 BY MS. GARCIA:

11 Q. Good afternoon.

12 A. I was just waiting for --

13 Q. Oh, for the send?

14 A. For a confirmation that it got there, but
15 I'll shutdown.

16 Q. You're -- you were trying to send the CV?

17 A. I did send the CV and I just -- I had asked
18 for a confirmation.

19 Q. Oh, oh, I called to make her aware that it's
20 coming.

21 A. Okay. Thank you. Let me shut this down.

22 Q. She'll let me know if it doesn't come.

23 A. Okay.

24 Q. So what we're talking about here is over the
25 lunch break you were able to get your

1 NACHTSHEIM

2 computer that had a copy of your CV on it and
3 you're going to give us an updated copy,
4 right?

5 A. Correct.

6 Q. Thank you very much.

7 A. And it was dated August 28th. I currently
8 updated it and then forgot -- promptly forgot
9 to send it, so I apologize for that.

10 Q. No problems. That's okay. That's why we
11 have a deposition.

12 Turning back to Exhibit 4, the
13 McGovern paper.

14 A. Okay.

15 Q. Let's get that in front of us again. Thank
16 you.

17 On page 1543, in the left column,
18 the first full paragraph beginning, "This
19 study does not establish a causal basis."

20 A. Yes.

21 Q. The second sentence in that paragraph ends
22 with the clause, "The data are observational
23 and may be confounded by other infection
24 control measures instituted by the hospital."
25 Do you see that?

1 NACHTSHEIM

2 A. Yes, I do.

3 Q. And are you familiar with hospital practices
4 concerning infection control?

5 A. Only -- only a little bit, yes. But, I mean,
6 I'm not intimately. Our -- my department at
7 the university has people who work in
8 infection control and quality and within
9 healthcare, so I hear talks about it.

10 Q. Okay. So you're aware, generally speaking,
11 that hospitals do make very concerted efforts
12 to control infection rates during surgery?

13 A. Absolutely.

14 Q. Do you have an understanding that infection
15 remains, to this day, an ineradicable risk
16 associated with surgery?

17 A. Yes.

18 MR. SACCHET: Objection;
19 foundation.

20 THE WITNESS: Well, I -- to this
21 day meaning it certainly hasn't been
22 eradicated?

23 MS. GARCIA: Yes.

24 THE WITNESS: Yes.

25 MS. GARCIA: That's what I meant.

1 NACHTSHEIM

2 Thank you for clarifying that.

3 BY MS. GARCIA:

4 Q. In a study designed to assess and compare
5 infection risk, would you agree with me that
6 it's very important to try to control for
7 differences in measures that might be taken
8 at the hospital where data is being collected
9 from to address infection risk?

10 A. It's -- it's important to -- are you asking
11 about collecting data on other factors that
12 might -- might be affecting --

13 Q. Yes.

14 A. -- infection risk?

15 Q. Well, let me be more specific. In the
16 McGovern paper, what is being compared is
17 infection risk observed during a time when
18 forced-air warming is used versus a time when
19 convective -- conductive fabric is used,
20 correct?

21 A. Correct.

22 Q. And if there were changes -- let me ask that
23 differently.

24 If there were differences in the
25 infection control practices being followed by

1 NACHTSHEIM

2 the hospital, that would be an important
3 factor that could impact the results?

4 MR. SACCHET: Objection; calls for
5 a medical opinion.

6 THE WITNESS: There -- there are
7 always -- you know, the problem with
8 observational studies is that there can be
9 other factors changing that could be
10 affecting results that you don't know about,
11 and so that's why -- that's basically why we
12 can't say we see a cause and effect.

13 BY MS. GARCIA:

14 Q. But even to make an observational study, even
15 to make an observational comparison, it is
16 important to account for factors that could
17 impact the results on which you're reporting?

18 A. You always want to do the best you can.

19 Q. And, in fact, that's discussed in the paper,
20 right?

21 A. Yes.

22 Q. So if we would look at the next sentence
23 after the one we were just looking at --
24 well, the clause we were just looking at
25 says, "The data are observational and may be

1 NACHTSHEIM

2 confounded by other infection control
3 measures instituted by the hospital." What
4 does that mean, "May be confounded by"?

5 A. Oh, I just found it again. So confounded
6 means that the variables, the factors,
7 whatever they are, are changed at the same
8 time. And if they're changed at the same
9 time, then if there's -- if we see a change
10 in a variable we're measuring, it could be
11 due to one, it could be due to the other, it
12 could be due to both, and we really have no
13 way of disentangling them when two variables
14 are confounded.

15 Q. So in this particular instance this is
16 referring to a change in warming unit
17 device -- I'm sorry, a change -- in this
18 particular instance, there's a change in the
19 patient-warming device being observed?

20 A. (Nods head.)

21 Q. Correct?

22 A. Correct.

23 Q. And there's the observation in the article
24 that there could also be confounding by
25 changes in infection control practices being

1 NACHTSHEIM

2 instituted at the hospital?

3 A. Correct.

4 Q. If the changes in infection control practices
5 are being instituted at the same time as the
6 change in choice of patient-warming system
7 and you see a difference in infection rates,
8 you can't determine whether that difference
9 in infection rates is due to the change in
10 infection control procedures, patient-warming
11 device or both?

12 MR. SACCHET: Object to form.

13 THE WITNESS: Correct.

14 BY MS. GARCIA:

15 Q. The next sentence says, "For example, changes
16 were made to the antibiotic and
17 thromboprophylaxis protocols used during the
18 study, although no infection control changes
19 were made after February 2010"; do you see
20 that?

21 A. Where -- same paragraph, right?

22 Q. Yes.

23 A. "For example, changes are made to the" --
24 okay, now I've got it. "Used during --
25 although no infection control," okay, I've

1 NACHTSHEIM

2 got it, right.

3 Q. Okay. After February 2010 is at the very
4 conclusion of the forced-air warming device
5 period, correct?

6 A. Correct.

7 Q. All of the conductive fabric warming device
8 period occurs after February 2010, correct?

9 A. Correct. All of the conductive fabric.

10 Q. Measurements are made?

11 A. Correct.

12 Q. Okay. Do you know how significantly
13 antibiotic and thromboprophylaxis protocols
14 connected to surgery have on infection rates?

15 A. I don't know.

16 Q. Is that something that you asked about?

17 A. I -- I was not involved in that part, so I --
18 I didn't ask about it.

19 Q. Well, when you say you weren't involved in
20 that part, what do you mean?

21 A. What I mean by that is simply that, you know,
22 it was -- it was important to address, as
23 best one can at least, are we aware of other
24 changes going on.

25 Q. And this would indicate there are changes

1 NACHTSHEIM

2 going on?

3 A. There are changes going on. And if that's
4 the case, one would want -- one would want to
5 take those into account as best one could.
6 But I was not involved in, you know, sort of
7 identifying the variables that might have
8 been changing. That all seemed to be part of
9 the job of the people at the hospital.

10 Q. Do you recall ever asking anyone either at
11 the hospital or Mark Albrecht or anyone else
12 how significant were the changes being made
13 to hospital infection protocols and how
14 likely were those to cause confounding?

15 A. I don't think I would put it as a question.
16 I think we certainly discussed the -- the
17 possibility that other things were changing
18 that could explain the -- the change in the
19 infection rates, but I didn't ask specific
20 questions about can you tell me what else
21 changed and when.

22 Q. Who did you discuss it with?

23 A. Mark. And, again, I didn't -- I didn't ever
24 ask him what changed, what else changed
25 besides this. We just -- we just talked in

1 NACHTSHEIM

2 general about could this be causal or we
3 e-mailed could this be causal or not, could
4 things be changing. And, I mean, I think we
5 agreed that yes, there could have been other
6 things changing that could explain this, we
7 just -- we don't know what they are.

8 Q. Well, would you expect that some of the
9 coauthors on the study know what they are?

10 MR. SACCHET: Calls for
11 speculation.

12 THE WITNESS: I -- they'd have a
13 better idea than I would, they're -- since
14 they're -- I think one or two was employed by
15 the hospital. They may have a better idea of
16 what's going on at the hospital, but I
17 certainly did not.

18 BY MS. GARCIA:

19 Q. Well, and you -- you were actually counting
20 on them to be knowing that information,
21 right?

22 A. Yes.

23 Q. That's something you believed they did know?

24 A. Yes, yes.

25 Q. Did the conversation with Mark about what

1 NACHTSHEIM

2 else might be changing, do you recall who
3 brought that up?

4 A. I don't know for sure. I think -- I know I
5 asked him at one point about, you know, what
6 are your thoughts on causality and so forth
7 in all this.

8 Q. I do have an e-mail that you might be
9 referring to, and let me see if I can find
10 that.

11 (Whereupon, Exhibit 19 was
12 marked for identification.)

13 BY MS. GARCIA:

14 Q. Exhibit 18 is --

15 MS. GARCIA: Is this 18? Let me
16 make sure I'm right.

17 THE COURT REPORTER: Nineteen.

18 MS. GARCIA: Nineteen. Okay.

19 Thank you.

20 BY MS. GARCIA:

21 Q. Exhibit 19 begins with an e-mail from Mark to
22 you on January 24th, 2011, forwarding a
23 New York Times article; is that correct?

24 A. Correct.

25 Q. Or a link to it, an Internet link to a

1 NACHTSHEIM

2 New York Times article. At the second page
3 you've responded to him, and at the top what
4 you say is, "Interesting article, even though
5 they were pretty hard on Scott. Hard to
6 disagree with the last quote where the guy
7 said that the data are compelling, but they
8 don't prove the link to infections in
9 practice and that a clinical trial would be
10 needed to do that"; do you agree? Is that
11 what you said?

12 A. I did.

13 Q. And that was your opinion at the time?

14 A. Yes.

15 Q. That remains your opinion today?

16 A. Yes.

17 Q. Are you referring here to the McGovern study?

18 A. Yes.

19 Q. Why would a clinical trial be needed to prove
20 a link to infections?

21 A. Excuse me. In the clinical trial, the
22 patients that are selected for the different
23 treatments are chosen -- are chosen at
24 random, so there's two things we need. We
25 need a large enough sample size and we need

1 NACHTSHEIM

2 to choose them at random. And the random --
3 the randomization mechanism gives us very
4 high assurance that the groups that we -- the
5 two different groups, think of a placebo and
6 treatment group, have roughly the same
7 characteristics, that they're balanced on
8 just about any demographic kind of feature
9 you could imagine, and that's because of the
10 random -- the random -- the random mechanism
11 by which they're chosen for the groups.

12 Q. And in connection to the McGovern paper,
13 would you mean a randomization for an
14 assignments either received forced-air
15 warming or conductive fabric warming?

16 A. Yes.

17 Q. Have you ever calculated the number of
18 patients that would be needed or the length
19 of time that a study would need to be
20 conducted in order to estimate -- or, I'm
21 sorry, in order to establish a causal
22 connection between the selection of
23 patient-warming device and infection risk?

24 A. I did not do that, never done that.

25 Q. If you look at Mark's response to you, he

1 NACHTSHEIM

2 says, "Yeah, I do agree with that"; is that
3 correct?

4 A. Yes, he does.

5 Q. Do you recall, outside of this e-mail
6 exchange, ever having a conversation with him
7 about this topic?

8 A. No.

9 Q. And are -- you were, in your mind, linking
10 this e-mail exchange to my questions about
11 the inability to sort out confounding by
12 infection control practices?

13 A. Right.

14 Q. Why is that? Why are you linking those two
15 things together?

16 A. Why am I linking those two things? Well,
17 the -- the -- you know, the achilles heel of
18 observational studies is that you -- you --
19 you can't ascribe cause and effect to
20 observational studies, whereas, in an
21 experimental study, clinical trials and
22 experimental study where randomization is
23 employed, we generally agree one can ascribe,
24 at least with very high levels of
25 probability, one can ascribe causal effect to

1 NACHTSHEIM

2 the result. So these are causal studies,
3 whereas, observational studies are generally
4 seeking association.

5 Q. And are you saying in your -- I just want to
6 be sure I'm understanding what you're saying.
7 In your mind, one of the primary
8 illustrations of that problem here was the
9 inability to correct for potential
10 differences in hospital infection control
11 measures?

12 A. Right, right. Yes.

13 Q. Thank you.

14 (Whereupon, Exhibit 20 was
15 marked for identification.)

16 BY MS. GARCIA:

17 Q. I also wanted to show you Exhibit 20, which
18 is an e-mail with some data attached, and the
19 first page of a draft manuscript. And I
20 guess -- you know, my question is actually
21 only about the e-mail.

22 A. Okay.

23 Q. Why don't -- I don't care if folks keep the
24 other pages, but for simplicity let's just
25 have the e-mail chain itself going from pages

1 NACHTSHEIM

2 1110 through 1115 be the Exhibit 20. So if
3 you could just remove the other pages. Could
4 you remove that clip, please?

5 A. (Complies.)

6 Q. Thank you. I just want to make sure we're
7 accurate here. Feel free to look at the
8 attached pages, and when you're done give
9 them back to me if you'd like so that --

10 A. I'll set them aside.

11 Q. -- so that we got a clear exhibit. Okay.

12 Exhibit 20, at the bottom of the
13 page --

14 A. The very first page, 1110?

15 Q. Yes, 1110, thank you.

16 A. Okay.

17 Q. So this begins on December 30th, 2010,
18 shortly before the e-mail we were just
19 discussing with Mark Albrecht writing to
20 Mike Reed, Paul McGovern and copying
21 Scott Augustine and you and attaching the
22 first official rough draft for the paper. Is
23 that correct, just what I've said so far?

24 A. Yes. So...

25 Q. So you could refer to the --

1 NACHTSHEIM

2 A. I'm -- I'm -- I'm --

3 Q. You could refer to the attachments then --

4 A. I'm -- I'm confused.

5 Q. Go ahead.

6 A. Sorry, maybe I wasn't listening well enough.

7 I was trying to read, this was to

8 Mark Albrecht --

9 Q. From Mark Albrecht.

10 A. Oh, the first one is --

11 Q. The top one?

12 A. Oh, yeah, the top one.

13 Q. From Mark Albrecht.

14 A. From Mark Albrecht, and I'm on that one.

15 Q. Okay. Yes.

16 A. Right.

17 Q. And, actually, I apologize, I'll clarify my

18 mind here. Go ahead and look at the

19 attachments and put them back with

20 Exhibit 20, because what I do want to confirm

21 is that this is referring to the paper that

22 became the McGovern paper, Exhibit 4.

23 A. So I don't know -- I have this one page at

24 the end --

25 Q. Yeah.

1 NACHTSHEIM

2 A. -- that's --

3 Q. And we can mark as Exhibit 21 the full thing.

4 A. And --

5 Q. That matches with that one page.

6 A. Okay. Because I'm not sure what's in this
7 paper.

8 Q. Yeah, go ahead and see Exhibit 21.

9 A. All right.

10 (Whereupon, Exhibit 21 was
11 marked for identification.)

12 THE WITNESS: (Reviews document.)

13 Right, so this paper did not lead to either
14 of these two papers.

15 MS. GARCIA: Okay.

16 BY MS. GARCIA:

17 Q. So Exhibit 21 is not the same. Really my
18 point is the bottom of the first page of the
19 e-mail.

20 A. Okay.

21 Q. So apparently maybe the draft is -- maybe I
22 don't have the draft right. But if we look
23 at Mike Reed's comments on the bottom of the
24 page, he says, "The infection reduction data
25 has been given too much prominence. Whilst

1 NACHTSHEIM

2 the data is real and can be used in the
3 discussion, it is potentially controlled by
4 many factors, and I am not prepared to imply
5 that this is solely an FAW effect. We have
6 made lots of interventions," dash, "it could
7 be any, although I agree it could largely be
8 an FAW effect." Do you see that there?

9 A. I do.

10 Q. And do you understand him to be raising the
11 same issue that you and I have just been
12 discussing about potential confounding?

13 A. Yes, it's the same issue.

14 Q. I see the issue we may have about the
15 attachment, because that e-mail came from
16 Mike Reed to Mark Albrecht and Paul McGovern
17 and then Mark forwarded it to you. Do you
18 see that?

19 A. Uh-huh. Yes.

20 Q. Okay. Did you ever have any communication
21 with either Mike Reed, Paul McGovern or are
22 Mark Albrecht about the prominence of the
23 infection reduction data in the article that
24 became Exhibit 4?

25 A. I -- I discussed it in as much as I was --

1 NACHTSHEIM

2 you know, I was given the data and we talked
3 about how to analyze it and -- and we talked
4 about, you know, how it came about and how it
5 was -- a little bit about how it was
6 collected, but -- but that's -- that's about
7 it.

8 I don't think that Mark and I got
9 into discussions about well, what are the
10 other variables that could have been changing
11 that are mentioned here. I mean, I guess
12 Mike Reed says there are other -- other
13 factors, I'm not -- I'm not -- I'm not
14 prepared to imply this is solely an FAW
15 effect. And in the paper they mention the
16 changes in the antibiotics, I guess.

17 Q. Right.

18 A. So --

19 Q. And they mention a few other things as well.

20 A. And I -- I just wasn't part of those
21 discussions.

22 Q. Okay. If we look at the first page of
23 Exhibit 4 we can see that Mike Reed is a
24 physician, correct?

25 A. Yes.

1 NACHTSHEIM

2 Q. And he's identified as the consultant
3 orthopedic surgeon?

4 A. How do you know that?

5 Q. I'm looking at the bar on the left-hand side.

6 A. Oh, at the paper. I'm sorry. Yes.

7 Q. Looking at Exhibit 4 on the first page.

8 A. Correct.

9 Q. He's identified as consultant orthopedic
10 surgeon?

11 A. Yes.

12 Q. Is there anyone else here identified as a
13 physician in connection with the -- the
14 hospitals or the healthcare systems in the
15 UK?

16 A. Well, Carluke and Partington --

17 Q. Okay.

18 A. -- orthopedic surgeons, but --

19 Q. Okay.

20 A. Yeah.

21 Q. Do you know the respective roles that those
22 played, Carluke and Partington?

23 A. I don't.

24 Q. Did it concern you that the physician who was
25 coordinating this study and whom you were in

1 NACHTSHEIM

2 e-mail communication with, at least as a copy
3 on many e-mails, was raising this issue that
4 they've made lots of interventions and he
5 doesn't know whether the observed change in
6 infection rate is due to those changes or due
7 to the choice of patient-warming system?

8 A. Does it concern me? It -- I wouldn't say I
9 have a major concern about this. I think
10 it's relevant to provide some data as long as
11 it's represented appropriately, and I
12 think -- I mean, when one -- when one thinks
13 back to things like smoking and cancer, we
14 never -- we were never able to run a clinical
15 trial on that, and so there's always
16 observational data. And so sometimes what's
17 required is many, many, many observational
18 studies and replication studies and so forth
19 to see, before someone really can kind of
20 come to the conclusion, well, yeah it's
21 probably causal.

22 Q. That is not really what I'm getting at.

23 A. Okay.

24 Q. What I'm getting at is when the gentleman who
25 is the physician leading the effort to do

1 NACHTSHEIM

2 this study is raising a concern that the
3 manuscript is giving too much impact to
4 infection reduction as between selection of
5 patient-warming device, given all the other
6 interventions that were happening at the
7 hospital, does that make you consider -- did
8 that make you at the time consider how are we
9 presenting these data and are we being fair
10 in our presentation?

11 MR. SACCHET: Objection to form.

12 THE WITNESS: I didn't -- I mean,
13 it certainly didn't occur to me to jump in at
14 that point and say I don't think we can
15 present that data, just because I thought
16 it's observational.

17 And as we move forward with the
18 paper my thought was let's -- you know,
19 let's -- we need to finish it, we need to
20 present it and say what we're going to say
21 about it and then people are going to weigh
22 in on whether that should be part of the
23 paper or not.

24 BY MS. GARCIA:

25 Q. Who would those people be?

1 NACHTSHEIM

2 A. Any of the authors.

3 Q. Okay. And -- well, you're one of the
4 authors.

5 A. I am.

6 Q. So when you say let's finish it and present
7 it, you mean present to each other?

8 A. That's what I meant.

9 Q. Okay. But you are presenting it to each
10 other here --

11 A. Uh-huh.

12 Q. -- and what Dr. Reed is saying is we're
13 putting too much emphasis on infection
14 control reduction -- or, I'm sorry, we're
15 putting too much emphasis on infection
16 reduction, because we really can't sort out
17 what's causing it.

18 A. What he's saying is I'm not prepared to imply
19 that this is solely an FAW effect. I mean, I
20 just read it. That -- that's what he's
21 saying.

22 Q. And do you understand FAW to stand for
23 forced-air warming?

24 A. Yes.

25 Q. And does he also say, "We have made lots of

1 NACHTSHEIM

2 interventions, it could be any, although I
3 agree it could largely be FAW effects"?

4 A. I understand that.

5 Q. He says that?

6 A. He said that. Yes, he said that.

7 Q. And you've mentioned quite a few times that
8 there's a difference between an observational
9 study and a randomized clinical trial and
10 somebody reading that would know it. But
11 there are times when even observational data
12 shouldn't be presented if you really can't
13 sort through and isolate the factor or the
14 variable that you're interested in.

15 MR. SACCHET: Objection; leading,
16 assumes facts not in evidence.

17 BY MS. GARCIA:

18 Q. Would you agree with that?

19 A. No, I actually do not agree with that. Let
20 me go back to what I tell my students when we
21 talk about regression correlation, and that
22 is that any time you have an association
23 you're doing -- sorry. Any time you're doing
24 an observational study, what comes out of
25 that are hypotheses.

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2 Q. Okay.

3 A. Okay. We don't get cause and effect, but we
4 get hypotheses, and those hypotheses, they're
5 hypotheses and they need further work.
6 And -- and maybe you follow up with an
7 experiment and you can prove it.

8 Like in this case maybe you would
9 follow up with a -- with a -- you know, with
10 a clinical trial. Maybe you can't. I mean,
11 there are plenty of situations where you
12 simply can't do it.

13 And -- and so -- and so one either
14 has to make a decision based on the
15 association whether you -- whether you
16 believe it's causal or not, you know, or just
17 say I don't -- you know, I just -- I
18 simply -- I don't want to act on that because
19 it's not of sufficient -- of a sufficiently
20 rigorous, sort of, level and I -- I don't
21 want to act on it.

22 And, remember, I teach -- I teach a
23 lot in a business school. And in business
24 it's often very difficult to run experiments
25 and so we're looking at past data and we're

1 NACHTSHEIM

2 looking at changes that were made in
3 management practice and we're trying to
4 understand did that cause something to
5 happen, did that -- did that change the way
6 we operate as a business, and we -- and we
7 never get that, that causation from those
8 kinds of empirical studies and so -- but
9 sometimes we have to act on it.

10 Q. Okay. And one thing you might do if you saw
11 an association, but you were concerned based
12 on factual information that there might be a
13 serious issue with confounding, is you might
14 decide to look back at your data and clarify
15 what do I know about these things that were
16 changing, and it might be very important, at
17 a minimum, to report that if you were
18 reporting your results; would you agree with
19 that?

20 MR. SACCHET: Object to form.

21 THE WITNESS: I would agree.

22 BY MS. GARCIA:

23 Q. In fact, have you ever understood that the
24 hospital at which these infection data were
25 collected was undergoing major efforts to

1 NACHTSHEIM

2 control infection rates during the time
3 period of the study reflected in McGovern,
4 Exhibit Number 4?

5 A. I -- I wasn't aware that this hospital had
6 more going on infection control-wise than
7 other hospitals, certainly wasn't aware of
8 that.

9 (Whereupon, Exhibit 22 was
10 marked for identification.)

11 BY MS. GARCIA:

12 Q. Have you ever seen Exhibit 22?

13 A. I have never seen Exhibit 22, no.

14 Q. Do you have -- do you see that this is
15 referring to Northumbria Health --

16 A. I do.

17 Q. -- Healthcare --

18 A. I'm sorry.

19 Q. -- NHS Foundation Trust?

20 A. Yes, I do.

21 Q. And do you see that that is also the location
22 or group with which Dr. Reed is affiliated,
23 on Exhibit 4?

24 A. It seems -- yes, I'm going to say it sure
25 seems the same to me.

1 NACHTSHEIM

2 Q. Okay. Do you see the statement, "During the
3 last two quarters of 2008, 2009, Northumbria
4 Healthcare NHS Foundation Trust was reporting
5 SSI rates in the combined total of surgeries
6 in THR, TKR and repair neck of femur between
7 3.5 to 5 percent and was regularly receiving
8 letters from the HPA informing the trust of
9 its high outlier status for SSI"?

10 A. I see that.

11 Q. And do you see, "As it was performing
12 approximately 2,200 hip and knee replacements
13 every year, implementing a robust
14 surveillance in SSI became a priority for the
15 orthopedic team and the Trust"?

16 A. I see that.

17 Q. Do you see on the second page there is a
18 large box diagram that takes up the bottom
19 half of the page that is labeled, "Trust wide
20 surgical site infection intervention timeline
21 for orthopedic THR and TKR surgery" --

22 A. Referring to --

23 Q. -- with a few more words after that?

24 A. You're referring to the -- the Figure 2?

25 Q. Yes.

1 NACHTSHEIM

2 A. Okay. Yes.

3 Q. And do you see where it says, "Figure 2," the
4 explanation for this diagram is, "The,"
5 quote, "timeline illustrates the
6 interventions undertaken from 2008 to present
7 day"?

8 A. Yes.

9 Q. And do you see that there are -- I know this
10 is -- I, at least, do not have eyes that can
11 read this diagram, but I can make out some of
12 the years in this diagram, and there are
13 changes being made in 2008, in 2009, in 2010,
14 in 2011, and then in later years; is that
15 right?

16 A. Yeah, I'm having a hard time reading it too,
17 but, yes.

18 Q. You can see those years?

19 A. Yeah, I can see the years.

20 Q. Do you see any indication in Exhibit 4 that
21 would give a reader any sense about the scope
22 and nature of the changes being made to the
23 infection control procedures at the hospital
24 or hospitals where the study took place?

25 MR. SACCHET: Object to form.

1 NACHTSHEIM

2 THE WITNESS: I'm sorry, can
3 you -- can you help me with that question a
4 little bit?

5 MS. GARCIA: Why don't we read it
6 back and see if you understand it.

7 (Whereupon, the last question
8 was read by the court reporter.)

9 THE WITNESS: I do see that there
10 are apparently a lot of changes going on.

11 BY MS. GARCIA:

12 Q. And that's not reflected the scope and
13 nature, that is not reflected in Exhibit 4;
14 would you agree with that?

15 A. I would agree with that.

16 Q. And if we -- I would like to give you a
17 moment to look at Exhibit 22, which is
18 titled, "Implementing Effective SSI
19 Surveillance," and which is reporting on how
20 the Northumbria Healthcare NHS Foundation
21 Trust reduced its infection rate within the
22 orthopedic department, and ask you if you see
23 any indication from the legible portions of
24 this article that reference a change in
25 patient-warming device being used?

1 NACHTSHEIM

2 A. (Reviews document.) Well, again, I'm afraid
3 I can't read all those boxes.

4 Q. Separate from the boxes, there's a lot of
5 text describing -- there's a lot of text
6 describing --

7 A. I can read the text, yes.

8 Q. So just take a moment and see if in the text
9 you see any reference to that.

10 A. (Reviews document.) Okay. I've -- I've kind
11 of skimmed it and I don't see any mention --

12 Q. Okay.

13 A. -- to the change in blanket.

14 MR. SACCHET: For the record, I'm
15 going to object and note that in the table in
16 the small print a difference is noted between
17 conductive fabric warming and forced-air
18 warming.

19 MS. GARCIA: I was just going to
20 point that out actually.

21 BY MS. GARCIA:

22 Q. I was -- I was looking at the table as you
23 were skimming, and I do see -- I don't know
24 if you can read it, so let me show you where
25 I'm looking, "Quarter 1, 2010."

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2 A. Okay.

3 Q. I'm not sure if that's quarter 1 or not.

4 Yeah. To the best of my ability, my eyes
5 would read this as, "A transition in
6 patient-warming systems from forced" --

7 A. Oh, I see it.

8 Q. -- "air to conductive fabric was made in all
9 three elective orthopedic theaters commencing
10 March 2010 and completing June 2010." Do you
11 see that?

12 A. I do.

13 Q. Okay. So that is one of three things noted
14 in quarter 1, 2010, correct, to the best of
15 my eyes?

16 A. Quarter 1, 2010, yes, best of three, right.
17 I mean, one of three.

18 Q. And I count 22 boxes on this graph. Do you
19 count a similar number?

20 A. In there.

21 Q. Roughly?

22 A. Approximately.

23 Q. Okay. And each box contains at least one
24 item?

25 A. Uh-huh.

1 NACHTSHEIM

2 Q. Yes?

3 A. Yes.

4 Q. And many boxes contain three or more items?

5 A. Correct.

6 Q. And in the two-and-a-half pages of text that
7 describe the changes that were made by this
8 team and the results that they saw, you have
9 not, in scanning it here today and reading
10 through it here today, seen any mention of
11 the change of patient-warming device; is that
12 right?

13 MR. SACCHET: Object.

14 THE WITNESS: I have not.

15 BY MS. GARCIA:

16 Q. And I would advise you that I don't see it
17 either, but do you see it?

18 MS. GARCIA: You're objecting?

19 MR. SACCHET: Oh, you used the
20 word text, so I would assume that text
21 implies the notation in the box.

22 MS. GARCIA: Oh, thank you. Okay.

23 BY MS. GARCIA:

24 Q. Setting aside the box, if we would look at
25 the two-and-a-half pages of narrative text

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2 that describes the efforts that were taken by
3 this team and the results that they saw, have
4 you seen here today any reference to the
5 patient-warming devices?

6 A. I do not see anything.

7 Q. Would you --

8 A. Outside of the -- outside of the Figure 2.

9 Q. Correct. And would you agree with me that
10 the focus of their description of their
11 efforts is the conduct of the surgical teams
12 and the conduct of their approach to surgery,
13 including things like what clogs they're
14 wearing, how they're washing themselves and
15 their clogs, how patients are being prepared
16 for surgery?

17 MR. SACCHET: I'm going to object
18 for foundation.

19 THE WITNESS: You know, I
20 don't have a good summary of all these
21 things, because I'm seeing -- I'm seeing
22 patient experience, 30-day phone calls,
23 surveillance -- I don't know how to -- I just
24 don't have time to --

25 MS. GARCIA: Okay.

1 NACHTSHEIM

2 THE WITNESS: I just don't have
3 time to summarize it all.

4 MS. GARCIA: To summarize it all,
5 sure.

6 BY MS. GARCIA:

7 Q. And if we look on page -- the second page of
8 the article, it starts off with, "The SSI
9 bundle"; do you see that?

10 A. I do.

11 Q. Do you understand SSI to mean surgical site
12 infection?

13 A. I did not understand that.

14 Q. Okay. You don't know that?

15 A. I don't know that.

16 Q. Okay.

17 A. But I --

18 Q. It's probably defined in here somewhere.

19 A. Here it is, "Surgical site infection," first
20 sentence.

21 Q. Okay.

22 A. Okay, now I understand it.

23 Q. And do you see that they first published what
24 they're calling an SSI bundle in 2009?

25 A. Uh-huh. Yes.

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2 Q. And it gave a, "Checklist and how-to guide
3 aimed not only at clinicians, but also at
4 managers and allied health professionals to
5 enable a multidisciplinary approach to the
6 worrying trend of increased SSIs"?

7 A. Yes, I see that.

8 Q. Okay. And then they go through two full
9 pages of describing the efforts that they're
10 doing. And do you see that at the present --

11 MR. SACCHET: I'm going to object
12 to the preamble and move to strike it.

13 BY MS. GARCIA:

14 Q. Would you agree with me that there are two
15 full pages here altogether of description in
16 narrative of the efforts that they're taking,
17 beginning at the, "SSI bundle," and going
18 through, "Patient experience" -- or, I'm
19 sorry, "30-day phone call," going through,
20 "30-day phone call," that's approximately two
21 pages of text?

22 A. Yes, it's approximately two, I agree.

23 Q. If you see the reference to the present on
24 the last page of the article, what is the
25 infection rate in 2014?

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2 A. Five percent to .9 percent, is that what --
3 "The SSI group has been successful in
4 reducing" -- oh, "Reducing the infection rate
5 from 5 percent to 0.9 percent April to June
6 2014."

7 Q. Do you know what time frame the April to June
8 2014 refers to, whether that's the total time
9 frame of the article, the time frame for
10 the .9 percent or some other thing?

11 A. The total time frame of this article?

12 Q. Yeah.

13 A. I don't know.

14 Q. Had you known about the --

15 A. And --

16 Q. Oh, go ahead. By context it has to be longer
17 than 2014, right?

18 A. Right. And I would very much like to know
19 what the standard errors of those statistics
20 are. They may tell me nothing.

21 Q. Okay. Well, nothing?

22 A. There may -- there may be no statistical
23 difference between 5 percent and .9 percent.
24 It all depends on the sample sizes they used
25 and how it was collected and so forth. I'm

1 NACHTSHEIM

2 just --

3 Q. Sure.

4 A. I'm just -- I just don't know what that
5 means.

6 Q. Fair enough.

7 If you had known the extent -- if
8 this does -- if this paper does reflect
9 changes that were made at locations where
10 infection data were gathered for
11 incorporation in Exhibit 4 --

12 A. Uh-huh.

13 Q. -- would you have wanted to provide more
14 detail in Exhibit 4 about the extent of these
15 changes?

16 MR. SACCHET: Objection;
17 foundation.

18 THE WITNESS: I think if -- I
19 think if we had known about these, and I
20 can't -- I mean, I can't comment on how --
21 how important one is versus another. I mean,
22 it could be none of these make any difference
23 whatsoever, I just don't -- I don't know.

24 But I certainly -- yes, I certainly
25 would have wanted perhaps more examples of

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2 changes that are going on if we had known
3 about it. I think that -- I think that helps
4 inform the reader, so, yes.

5 BY MS. GARCIA:

6 Q. Have you ever seen any analysis of -- if we
7 go back to Exhibit 4, there's a reference to
8 the -- other than a general reference to
9 other -- okay. Let me -- let me start over
10 and get clear.

11 In Exhibit 4, on that same page
12 we've been looking at, 1543, there is a
13 general statement that, "The data are
14 observational and may be confounded by other
15 infection control measures instituted by the
16 hospital," there's that reference, and then
17 there's a, "For example," and it says,
18 "Changes were made to antibiotic and
19 thromboprophylaxis protocols used during the
20 study," right --

21 A. Right.

22 Q. -- just to get us regrounded?

23 A. And I remember that sentence, but I forgot
24 where you are right now.

25 Q. Okay. Page 1543.

1 NACHTSHEIM

2 A. Oh.

3 Q. So the two changes are that specifically
4 identified in this article are antibiotic and
5 thromboprop -- prophylaxis protocols, right?

6 A. Yes.

7 Q. Are you aware of any analysis of the data
8 about infections that was used to create
9 Exhibit 4 that holds constant the antibiotic
10 and thromboprophylaxis protocols and then
11 compares a patient-warming device during a
12 period when they had comparable drug use?

13 A. No.

14 Q. If it were the case that when the drug use,
15 both antibiotic and anticlotting drugs, are
16 the same, the two patient-warming devices,
17 forced air or conductive fabric, also have
18 the same infection rate, would that be
19 important for you?

20 MR. SACCHET: Object to form.

21 THE WITNESS: Yes, that would -- I
22 think that -- that's -- that's important. I
23 think that that's the kind of thing that
24 should be reported.

25 BY MS. GARCIA:

1 NACHTSHEIM

2 Q. And why is that?

3 A. You've just described a situation where two
4 variables are -- are confounded. And so from
5 the data -- I mean, if they're perfectly
6 confounded in that fashion, we cannot --
7 again, it may have been one factor, the other
8 factor or a combination of the factors that
9 led -- and it could be something else besides
10 that.

11 Q. Okay.

12 A. I mean, there could be other interventions or
13 other changes that led to these -- led to
14 changes --

15 Q. Sure.

16 A. -- as well.

17 Q. But you just don't know?

18 A. But I just don't know. If I had known
19 that -- if I knew that there -- that there
20 was a change that was sort of coincident, I
21 think it would be worth reporting.

22 Q. Let me be clear in my question. I am not
23 asking you to assume that the change in drug
24 protocol was made exactly at the same time --

25 A. Okay --

1 NACHTSHEIM

2 Q. -- that the warming device selection was
3 made. I'm asking you -- although that --
4 that could be a different question.

5 If you were able to sort through the
6 data and determine that there -- there were
7 data collected at a time when the two drugs
8 were the same for the forced-air warming and
9 for the conductive fabric, and when the drug
10 use was the same, those two warming devices
11 were -- had the same infection rate, would
12 that be important to you?

13 MR. SACCHET: Object to form.

14 BY MS. GARCIA:

15 Q. Even if the change wasn't made at the same
16 time?

17 A. So let me make sure I understand your
18 question. So -- which stayed constant?
19 The -- the drug stayed constant?

20 Q. No, the drug actually changed twice. What I
21 understand based on Mark Albrecht's testimony
22 is that there was -- and also based on other
23 documents I've seen, that there was a change
24 in the antibiotic.

25 A. Yes.

1 NACHTSHEIM

2 Q. There was also a change in the anticlotting
3 drug, and then -- then the anticlotting drug,
4 they went back to what they had originally --
5 they went back to -- let me figure out how to
6 say this, because I'm not sure I have the
7 details perfectly correct. But what I
8 understand from Mark Albrecht's testimony is
9 that there is a way to isolate the
10 patient-warming unit so that there was a time
11 in which forced-air warming was used with a
12 particular regimen with both antibiotic and
13 prophylaxis clot control, and there was a
14 time when conductive fabric warming was used
15 with the same drug protocol, and at that time
16 the infection rate was the same between the
17 two devices. Is that important to you?

18 MR. SACCHET: Object to form.

19 THE WITNESS: Oh, boy. So there's
20 certainly -- dang. So the -- the -- we went
21 from -- there was -- I'm sorry, you said
22 there was a time when -- I'm wondering, did
23 we -- did we change the -- or the -- the
24 blanket?

25 BY MS. GARCIA:

1 NACHTSHEIM

2 Q. We are comparing the use of forced-air
3 warming --

4 A. To --

5 Q. -- with a particular drug regimen --

6 A. Okay.

7 Q. -- with the use of conductive fabric warming
8 with the same drug regimen --

9 A. With the same drug regimen.

10 Q. -- and those two warming devices have the
11 same infection rate. That's important, isn't
12 it?

13 MR. SACCHET: Object to form.

14 THE WITNESS: So there's a subset
15 in time, in other words, when the -- okay,
16 when the forced air and the conductive fabric
17 have the same infection rates and the drug
18 hadn't changed in those -- or the --

19 BY MS. GARCIA:

20 Q. The drugs -- you could compare a time, you
21 could isolate and compare a time where they
22 had the same drug regimen, yes.

23 A. Yeah. Is that important to me?

24 Q. Yeah.

25 A. I certainly think it would be interesting

1 NACHTSHEIM

2 and -- and -- and we could analyze that. I
3 mean, that's -- there are ways to analyze
4 that.

5 Q. And you would want to analyze that before
6 presenting to the public a paper that says,
7 we saw this drop in infection rate when the
8 patient-warming device, was made?

9 A. I certainly would want -- again, you may
10 not -- you may not be able to -- to -- when
11 you -- when you're cutting down -- when
12 you're cutting this interval into smaller
13 intervals where -- where the -- the drug was
14 the same, but the treatment -- but the -- but
15 the conductive fabric was different, you may
16 be in a very small area, you might not be
17 able to show statistically significant
18 differences. I mean, you have very little
19 power. I'm just saying yes, I'd want to look
20 at it if I had that data. I mean, I think
21 I'd want to -- I'd want to eliminate --
22 again, it goes back to wanting to eliminate
23 as much as you can confounding effects.

24 Q. And would -- would you --

25 A. Absolutely.

1 NACHTSHEIM

2 Q. -- agree that because the drug regimens are
3 specifically mentioned in the paper, that's
4 something that the team of authors considered
5 important to infection risk?

6 MR. SACCHET: Object to form.

7 THE WITNESS: I think -- yeah, the
8 way -- how is it stated again? It was on
9 page --

10 MS. GARCIA: 1543.

11 THE WITNESS: 1543.

12 (Reviews document.)

13 MR. SACCHET: I'll add foundation
14 too.

15 THE WITNESS: "For example,
16 changes made to the antibiotic
17 thromboprophylaxis protocols used during the
18 study, although no infection control changes
19 were made after February 2010." If you're
20 asking should there have been -- have been an
21 analysis done, we -- statisticians generally
22 want to do more analysis the better, we want
23 to answer all the questions we can.

24 I suppose that when I read that I
25 came to the conclusion that we didn't have

1 NACHTSHEIM

2 sufficient -- that the -- that other people
3 from the hospital who knew this data better
4 than I did concluded that these are examples
5 of other things that changed and we really
6 couldn't carry out -- we weren't going to
7 have the data to carry out the analysis.

8 BY MS. GARCIA:

9 Q. If you had known the data were there, you
10 would have wanted to carry out the analysis?

11 A. I -- I think -- I think, yeah, I would have
12 wanted to carry out the analysis.

13 Q. And if the results showed that when you could
14 control for the drug regimen by comparing
15 like to like, the patient-warming devices
16 were no longer different from each other,
17 that would be relevant to a reader of this
18 paper based on the statements that are made
19 in this paper, Exhibit 4?

20 MR. SACCHET: Object to form.

21 THE WITNESS: It might be
22 relevant -- it would be relevant. If we
23 saw -- if we saw no difference we would also
24 have to conduct what's called a power
25 analysis to say did we really have sufficient

1 NACHTSHEIM

2 data in these windows to make any kind of
3 conclusion.

4 MS. GARCIA: Okay.

5 BY MS. GARCIA:

6 Q. Going back for a moment to the bubbles --
7 actually, I'm going to set this aside for a
8 moment. I need to talk with you about the
9 other paper. I think I would like to get to
10 the other paper for a moment.

11 Well, actually, I wanted to show you
12 this just as a final --

13 (Whereupon, Exhibit 23 was
14 marked for identification.)

15 BY MS. GARCIA:

16 Q. I don't believe I have a colored -- I -- I
17 would have brought it had I thought I had a
18 colored version. But Exhibit 23 --

19 MS. GARCIA: Is that right?

20 THE COURT REPORTER: (Nods head.)

21 MS. GARCIA: Thank you. I'm
22 sorry, somehow my exhibits are disappearing.

23 BY MS. GARCIA:

24 Q. Exhibit 23 is an e-mail from you to
25 Mark Albrecht forwarding your edits to the

1 NACHTSHEIM

2 McGovern paper; is that correct? And I have
3 both the e-mail and the attached redline as
4 part of Exhibit 23.

5 Actually, let -- let me clarify my
6 question. The first line of your e-mail
7 says, "Attached are some additional small
8 changes tracked in blue," correct?

9 A. Yes.

10 Q. And then there is a copy of a redline
11 manuscript, although we don't have the color
12 available, is that right, here in this room?

13 A. Okay. So I think you were asking if this was
14 the McGovern paper?

15 Q. Yes.

16 A. And it looks like it is, yes.

17 Q. And if we looked on the first page of the
18 attachment, which has the ending number 727,
19 there's a redline to Dr. Belani's e-mail
20 address. Would you have made that?

21 A. No.

22 Q. So that's why I'm wanting to clarify. I
23 think this document might contain some
24 redlines from more people than just you. But
25 do you believe that this document contains

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2 the edits you did make?

3 A. So I just found -- finally found some that
4 I'm pretty sure I put in there.

5 Q. Okay.

6 A. There were other changes where it was
7 possible, but they were a little more
8 generic, these having more to do with the
9 statistical analysis.

10 Q. So are you on page 734 where you think you
11 made the redlines?

12 A. Yes.

13 Q. And those are in the, Statistical Analysis,
14 section?

15 A. Yes.

16 Q. Page 736, in the, Joint Substance Rates,
17 section, there is a section about
18 asymptomatic, and I think you referenced that
19 as having deleted it in your e-mail?

20 A. Uh-huh. Yes. I'm just trying to locate it
21 here.

22 Q. Page 736 in, Joint Sepsis Rates.

23 A. Joint Sepsis Rates. (Reviews document.)

24 Right, I see it now.

25 Q. At the end of that paragraph there's some

1 NACHTSHEIM

2 revisions to a sentence about the antibiotic
3 regimen and the thromboprophylaxis protocol.

4 Do you believe you made those changes?

5 A. To me that's a fairly cosmetic change, and I
6 might have made it, but I -- I can't say for
7 sure.

8 Q. Okay. Looking at page 746.

9 A. Okay.

10 Q. Below the figure there's a statement redlined
11 in, "Mark, you don't mean standard error here
12 because the interval is not symmetric, you
13 really mean upper and lower XX percent
14 confidence limits for the mean, I think." Do
15 you believe you --

16 A. I made that.

17 Q. You did?

18 A. I did.

19 Q. Okay. Is there any other edits you believe
20 you've ever made to the McGovern paper that
21 are not reflected in this document?

22 A. I don't think of substance. And -- and --
23 and maybe I -- I know I made more than just
24 those two or three that we talked about, but
25 I know there were a lot of cosmetic changes

1 NACHTSHEIM

2 that I suggested. And -- and by a lot I mean
3 like nine or ten or something like that.

4 Q. Okay.

5 A. But I don't think anything of substance.

6 Q. Okay. So they may or may not be included in
7 here, but the only other changes that we
8 don't see in this document would be very
9 minor?

10 A. It would be -- I think they would be very
11 minor, right.

12 Q. Okay. Thank you. All right.

13 I'd like to switch for a moment to
14 the Belani paper, Exhibit 5.

15 A. I know I've messed up one of these exhibits.

16 Q. Oh, do you need help?

17 A. I need help. I mean, I've got -- I've got --

18 Q. I think those two just get clipped together,
19 the two you're holding in front of you.

20 A. These just get clipped together?

21 Q. Well, let me -- let me clarify.

22 A. It's Exhibit 20.

23 Q. Oh, 20? Okay. Let me check on that.

24 According to my record, Exhibit 20 has the
25 first as an e-mail with 1110 on the bottom.

1 NACHTSHEIM

2 A. Yes.

3 Q. And then there is several items, then there's
4 data --

5 A. 1127, 28, 29, 30.

6 Q. 3/12/06, and it ends on a single page.

7 A. 1130.

8 Q. Yup, 1130. Yup?

9 A. And 1199, 1200, 1201 --

10 Q. Yup.

11 A. -- 1206.

12 Q. Yes, and that's the last page.

13 A. Oh, good.

14 Q. So if you clip those together, you'll be
15 perfect.

16 A. I'm stunned.

17 Q. You got it.

18 What was 21? Oh, 21 was a copy of
19 the paper.

20 MR. SACCHET: Was the paper, yeah.

21 MS. GARCIA: Yeah. Thank you.

22 So let's mark one more.

23 (Whereupon, Exhibit 24 was
24 marked for identification.)

25 BY MS. GARCIA:

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2 Q. Exhibit 24 is an e-mail chain, and on the
3 second page is a January 27, 2011, e-mail
4 from Mark to you saying, "Chris, I also have
5 two more in progress that I'm currently
6 writing up that you certainly could be a part
7 of. The first deals with temperature
8 increases in the laminar flow field due to
9 forced-air warming use."

10 And then I want to skip that, and
11 then the second says -- second study, "We
12 recently completed at the University of
13 Minnesota Hospital two weeks ago assessing
14 laminar flow disruption in the hospital
15 there. I'll show you the videos from that
16 one when we get together sometime. Since
17 this was done on your home turf, so to speak,
18 it would be fun to have you as an author on
19 this one also. The doctors I did this with
20 were Kumar Belani and Paul McGovern." Do you
21 see that?

22 A. Yes.

23 Q. Do you believe that this was your first
24 notice of the work that became Exhibit 5, the
25 Belani study?

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2 A. Yes.

3 Q. Did you ever have a conversation with
4 Mark Albrecht or any kind of communication
5 with him about this study before January 27,
6 2011?

7 A. Not that I recall, no.

8 Q. So when he first spoke to you about it, the
9 experimental work had already been conducted?

10 A. Yes.

11 Q. Do you recall at any time giving
12 Mark Albrecht any feedback, insight, comments
13 about the design or analysis that is
14 reflected in Exhibit 5?

15 A. I remember -- I believe I remember kind of
16 looking at the data after it had been in and
17 talking about how to present it and so forth,
18 but the experiment had been carried out, I
19 believe, so I -- I guess I was more
20 consulting on the analysis.

21 Q. And I am -- just to be clear, you produced
22 hundreds of documents that I am in no way
23 representing that I brought all of them down
24 here. I had to make choices about which ones
25 I wanted to ask about. So there may well be

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2 a document in which you're providing comments
3 on this study and I don't have a current
4 recollection of that sitting here.

5 But I'm just wondering separate
6 from -- and, obviously, the documents are
7 whatever they are. Separate from whatever
8 the documents would show, do you have any
9 memory, and I'm thinking of the one you
10 shared earlier this morning, about observing
11 the laminar flow study that you observed, you
12 had some comments on the way that was done,
13 do you have any memory about the way this
14 study was done?

15 A. No.

16 MR. SACCHET: Object to form.

17 THE WITNESS: I -- I don't have
18 any memory of commenting on sort of the
19 design or the execution of this.

20 BY MS. GARCIA:

21 Q. And in terms of the statistical analysis, do
22 you have any memory concretely about what you
23 may have said?

24 A. I don't have any particular memory about it.

25 Q. Okay.

1 NACHTSHEIM

2 A. It's -- I will say the analysis is going to
3 be very, very similar to -- to the one that
4 was carried out in the other paper.

5 Q. Okay. If you'd turn to the last -- well,
6 page 410 of Exhibit 5. I'm sorry, it's not
7 the last page, it's the last page with text
8 on it --

9 A. Got it.

10 Q. -- other than with references.

11 The first full paragraph in the left
12 column says, "It is worth mentioning,
13 however, that the observed disruption was
14 dependent on our exact setup, i.e.,
15 arrangement of draping, lights and personnel,
16 which did not include the presence of
17 instrument trays and a working surgical
18 team." Do you see that?

19 A. Yes.

20 Q. And then the next sentence is, "Thus, we are
21 unsure of the exact degree of ventilation
22 disruption that might occur in a working OR
23 during orthopedic surgery." Do you see that?

24 A. I do.

25 Q. Did you recall -- do you recall having read

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2 those statements when you reviewed the
3 article?

4 A. Yes.

5 Q. Do you agree that including statements like
6 that are important?

7 A. Yes.

8 Q. And why is that?

9 A. I think it's always important to identify
10 the -- there are always study limitations and
11 it's important to identify them. It can spur
12 either -- additional research by people who
13 read the article in replication follow-up and
14 so forth.

15 Q. And in particular here, would this kind of a
16 limit mean that the results from the study
17 reported in Exhibit 5 --

18 A. Okay.

19 Q. -- could not be generalized to other
20 situations, even an operating room in the
21 University of Minnesota Hospital during
22 actual surgery?

23 MR. SACCHET: Object; foundation.

24 THE WITNESS: I think -- in a --
25 in a very strict sense we -- we can talk

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2 about the experiment we ran and the changes
3 we ran and -- and the experimental setup, and
4 one can always say well, my -- my room is
5 shaped differently, where -- where someone is
6 standing is going to be different, and that
7 might or might not have an impact on the
8 results.

9 BY MS. GARCIA:

10 Q. Well, and specifically here, one of the
11 things that's commented on, if we go to that
12 same first full paragraph on the left column,
13 the experimental setup in this study didn't
14 include an instrument tray or a working
15 surgical team, right?

16 A. Correct.

17 Q. So during an actual surgery would you expect
18 there to be instrument trays and a working
19 surgical team?

20 MR. SACCHET: Objection;
21 foundation.

22 THE WITNESS: I'm really not an
23 expert on that. I mean, as a layperson, I
24 would probably expect that, yes.

25 BY MS. GARCIA:

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2 Q. I mean, certainly you would agree that there
3 has to be a surgical team if there's a
4 surgery?

5 A. I would agree with that, yes. I was thinking
6 about the tray.

7 Q. The tray, the instrument tray, okay.

8 But there would be -- the fact that
9 they're identifying in here instrument trays,
10 would indicate to you that there are
11 instrument trays involved in surgery?

12 A. Right.

13 Q. And if you read it further down in that
14 paragraph, there's a discussion of, "The
15 head-end surgical light being positioned
16 close to the raised anesthesia drape
17 attributable to the height of our surgeon,
18 six foot three inches, who needed sufficient
19 head room to operate. Thus, for shorter
20 surgeons, different results might be
21 expected." Do you see that?

22 A. I do.

23 Q. So here they're not only identifying the
24 presence of a surgical team that's working,
25 they're saying even the height of the doctor

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2 we've got might affect the airflow we're
3 observing, right?

4 A. Exactly.

5 Q. Okay. So --

6 A. If I could add --

7 Q. Yes.

8 A. -- it might and it might not.

9 Q. Sure.

10 A. We just don't know.

11 Q. We don't know. Well, the -- and the wording
12 is, "Might be expected," right?

13 A. Right. Exactly. Right. But I'm just saying
14 I don't want to say we would expect to see
15 changes if we had a different surgeon.

16 Q. Sure.

17 A. I can't say that as a result of this, but I
18 can say it's a possibility.

19 Q. And it's a possibility significant enough
20 that it was referenced in the paper?

21 A. Yes.

22 Q. And then the next thing that's referenced in
23 the paper is saying, "It was necessary to
24 turn surgical lights off during the
25 experiment to allow for consistent bubble

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2 counts in the intersecting light plane.

3 Given that lighting heat sources tend to
4 adversely affect ventilation performance, our
5 results should be considered conservative."

6 Do you see that?

7 A. Yes.

8 Q. So lighting is going to make a difference?

9 MR. SACCHET: Object; foundation.

10 THE WITNESS: Lighting might
11 possibly make a difference.

12 MS. GARCIA: Okay.

13 THE WITNESS: I agree.

14 BY MS. GARCIA:

15 Q. There is a conclusion here that says,
16 "Therefore," on the last paragraph, "It
17 seems" -- oh, I'm sorry, before we get to the
18 last paragraph, the next paragraph talks
19 about the positioning of the surgical lights,
20 whether it's either in line with the OR table
21 or at the sides of the OR table, which varies
22 by practice in different countries; do you
23 see that?

24 A. I -- "lights were positioned to the sides of
25 the OR table in the Netherlands study," I see

1 NACHTSHEIM

2 that. Are you in the -- are you in the --

3 Q. Yeah, you're right there.

4 A. Okay. Yeah.

5 Q. In the above paragraph -- I'm sorry, I'm
6 going backwards. Just -- we're climbing up
7 here.

8 "The most recent articles published
9 on the association between Patient Warming
10 Excess Heat: Ventilation Disruption, present
11 contradictory conclusions. Two studies in
12 the UK have characterized the airflow
13 patterns," I'm paraphrasing here a little
14 bit, "Supporting the physics behind
15 ventilation disruption in laminar flow ORs,
16 and then in contrast a published study in the
17 Netherlands found no evidence of ventilation
18 disruption due to forced-air excess heat when
19 evaluated with a particular standard that's
20 identified by number"; do you see that?

21 A. I see that.

22 Q. And then there's further comments about these
23 differences in placement of the lights,
24 there's comments about differences in the
25 release of bubbles. And the concluding

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2 paragraph is, "Therefore, it seems that
3 future research is warranted to characterize
4 the clinical conditions under which
5 forced-air warming excess heat results in
6 ventilation disruption during surgery."

7 Would you agree with that statement?

8 A. I agree.

9 Q. And the -- the factors they're identifying
10 that one should account for are draping,
11 ventilation airflows, flow obstructions
12 including lighting, instrument trays and
13 personnel movements, each of which has been
14 identified as affecting the phenomenon; do
15 you see that?

16 A. I do.

17 Q. Do you agree with that?

18 MR. SACCHET: Objection;
19 foundation.

20 THE WITNESS: I'm -- I'm -- it's
21 beyond -- it's been a long time and so I'm a
22 little bit unclear. It says that all these
23 things, draping, ventilation -- draping for
24 sure, we -- we've done that in some of the
25 experiments. Ventilation airflow, flow

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2 obstructions, personnel movements and all
3 those things, I'm presuming that we were
4 referring to some other studies, because it
5 wasn't part of our -- wasn't part of our
6 work.

7 MS. GARCIA: Right.

8 THE WITNESS: And I wasn't aware
9 that any of the studies had included
10 personnel movements and -- and different
11 ventilation airflows. I'm not saying they
12 weren't, I'm just saying I'm not aware of
13 that.

14 BY MS. GARCIA:

15 Q. Would you agree that the Belani study by
16 itself does not establish that the use of
17 forced-air warming causes any impact on the
18 airflow in an active surgical operating room?

19 MR. SACCHET: Object to form.

20 THE WITNESS: Would I -- please
21 read the question.

22 (Whereupon, the last question
23 was read by the court reporter.)

24 THE WITNESS: That the Belani
25 study --

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2 (Whereupon, the last question
3 was read by the court reporter.)

4 THE WITNESS: I'm not sure what
5 basis I have to make that conclusion. It
6 certainly seems to establish that under
7 certain conditions it -- there's an effect on
8 airflow.

9 MS. GARCIA: Okay.

10 BY MS. GARCIA:

11 Q. And whatever -- that's the experimental
12 conditions reflected in the paper?

13 A. Right.

14 Q. Okay. And are you, though -- the paper
15 itself expresses as a limit that it is not
16 able to -- the paper itself expresses the
17 limit that the results are dependent on the
18 exact setup of the experiment, right?

19 A. I think -- I think we're saying it's -- yes,
20 to a certain degree. We're very -- we're
21 aware of the fact that moving -- moving
22 people around and so forth could lead to
23 different -- different results, could
24 potentially lead to different results.

25 Q. Well, the sentence in the article is, "It is

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2 worth" -- let's get there together. Left
3 column. "It is worth mentioning" --

4 A. Wait a minute.

5 Q. Oh, sorry.

6 A. Where are we again? "It is worth
7 mentioning," okay, got it.

8 Q. "It is worth mentioning, however, that the
9 observed disruption was dependent on our
10 exact setup, i.e., arrangement of draping,
11 lights and personnel, which did not include
12 the presence of the instrument trays and a
13 working surgical team, thus, we are unsure of
14 the exact degree of ventilation disruption
15 that might occur in a working OR during
16 orthopedic surgery," right, that's what the
17 article says?

18 A. Yeah, it does say that, and my name is -- my
19 name is on this paper. I think -- I think
20 that sentence was just a little bit too
21 strong, because they say that the observed
22 disruption -- disruption was dependent on our
23 exact setup.

24 Q. Uh-huh.

25 A. We really didn't show that. You would need

1 NACHTSHEIM

2 to use a different setup or you'd need to
3 change that setup and see changes to say
4 that -- you know, that we've demonstrated
5 that it's dependent on this exact setup. I
6 think what -- what's -- what's really being
7 said here is that there's a possibility that
8 changing the setup will change the results.

9 Q. That's actually an excellent point that I
10 wanted to ask you about.

11 Are you aware of how many different
12 setups they tried before arriving at the one
13 that was used to generate the data reflected
14 in this paper?

15 MR. SACCHET: Asked and answered.

16 THE WITNESS: I have -- yeah,
17 it's -- I -- I'm not aware.

18 MS. GARCIA: Okay.

19 BY MS. GARCIA:

20 Q. And if one were to draw conclusions about the
21 impact of forced-air warming devices on
22 surgical operating rooms in general, separate
23 from the exact experimental setup represented
24 here --

25 A. Okay.

1 NACHTSHEIM

2 Q. -- would it be important to conduct some
3 additional experiments to change some of
4 those variables and see how replicable the
5 results were?

6 A. I think so, yes.

7 Q. And is the importance of that highlighted by
8 some of the different results that are
9 reported in the context of the rest of this
10 paper?

11 MR. SACCHET: Object to form.

12 THE WITNESS: I -- I think we're
13 saying that that's something that's -- that
14 could very well impact how all this works.

15 BY MS. GARCIA:

16 Q. So based on the work that is reported in
17 Belani and the work that is collected in
18 Belani from other papers, would one be able
19 to take away any particular expectation that
20 they could apply to their own operating room
21 and say this work tells me what I'm going to
22 see if I use a forced-air warming device in
23 my operating room?

24 MR. SACCHET: Object to form,
25 object to foundation, calls for a medical

1 NACHTSHEIM

2 opinion.

3 THE WITNESS: Well, I think we
4 know that when you say, "In my operating room
5 it's going to be different," then it's
6 probably going to be -- there has to be some
7 differences. And so could those differences
8 lead to different -- changes in the way
9 things are disrupted or if they're disrupted
10 at all, well, we certainly can't answer that
11 from this study and -- and so someone
12 would -- someone could probably say my -- my
13 operating room is set up a little
14 differently, so this doesn't apply to me.
15 But there's -- we don't have any -- we don't
16 have data that -- that says that is
17 necessarily the case.

18 BY MS. GARCIA:

19 Q. We don't know one way or the other?

20 A. We don't know one way or the other.

21 Q. The Belani study does not report on any
22 infection risk at all --

23 A. Right, no.

24 Q. -- at the University of Minnesota Hospital,
25 correct?

1 NACHTSHEIM

2 A. No.

3 Q. I'm sorry, that was a bad question, because I
4 said correct and you said no.

5 A. I'm sorry. My fault.

6 Q. Does -- no, it was mine.

7 Does the Belani study report on any
8 infection data at all?

9 A. No.

10 Q. Thank you.

11 Would you agree with me that the
12 Belani study does not establish that the use
13 of a forced-air warming device to warm
14 patients during surgery causes any increase
15 in infection risk?

16 MR. SACCHET: Object to form.

17 THE WITNESS: It does -- it does
18 not show any increase in infection rates.

19 BY MS. GARCIA:

20 Q. That's what you agree with?

21 A. I agree with that.

22 Q. And would you agree that that is true whether
23 we look at the Belani study alone or whether
24 we look at it also in connection with the
25 other papers cited within it?

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2 MR. SACCHET: Object to
3 foundation.

4 THE WITNESS: The last phrase
5 threw me a little bit, because you mentioned
6 all the other papers mentioned within it.

7 MS. GARCIA: There's a reference
8 list attached to --

9 THE WITNESS: But I would say
10 that -- I don't -- hold on. I don't recall
11 that any of the other papers that are
12 mentioned actually have -- have a -- even
13 looked at infection rates or certainly didn't
14 establish any causal links, infection rates.
15 Again, that comes back to needing to do a
16 clinical trial of some kind.

17 Q. I don't believe I asked you -- with respect
18 to going back again to Exhibit 4, McGovern.
19 We've talked a lot about the bubbles in
20 general, but I don't believe I asked you, I
21 just want to be clear, the same limits that
22 we just talked about for the Belani paper
23 about whether or not the observed effects on
24 airflow in an operating room -- I'm sorry,
25 let me ask this again.

1 NACHTSHEIM

2 I apologize if I've already asked
3 this before, but then let's strike that
4 predicate and let me just start a clean
5 question, which is, the McGovern paper,
6 Exhibit 4, does also report on impacts on
7 airflow that are observed through bubble
8 counting depending on the warming device
9 used, correct?

10 A. Correct.

11 Q. For the same reasons we discussed in
12 connection with the Belani paper, Exhibit 5,
13 is it correct to say that one would not know
14 if what was observed in the McGovern study
15 would apply to some active operating surgical
16 room?

17 MR. SACCHET: Object to
18 foundation.

19 THE WITNESS: In the same way, I
20 think that's correct. There was -- there was
21 one particular setup in that paper. I mean,
22 they changed the height of the drape, but
23 otherwise there was one setup and -- and so
24 the same qualifications apply.

25 MS. GARCIA: I think I may be

1 NACHTSHEIM

2 done, but if -- why don't we go off the
3 record for five minutes and just let me
4 review my notes and check in with Deborah
5 real quick, if that would be okay.

6 THE VIDEOGRAPHER: We're going off
7 the record at 3:21 p.m.

8 (Whereupon, a brief recess
9 was taken.)

10 THE VIDEOGRAPHER: This is
11 video number 5 in the deposition of
12 Christopher Nachtsheim. Today is November
13 29th, 2016. We're going back on the record
14 at 3:30 p.m.

15 MS. GARCIA: Professor Nachtsheim,
16 thank you, I have nothing further.

17 Do you have questions?

18 MR. SACCHET: I do.

19 MS. GARCIA: Okay. I just wanted
20 to make clear, under the Federal Rules of
21 Civil Procedure you do have an ability to
22 read the transcript and make any corrections
23 that you feel are needed. You have the
24 opportunity to waive that right. And at the
25 conclusion of today, you just let us know

1 NACHTSHEIM

2 what you would prefer, or now, just let us
3 know if you'd prefer to read the transcript.

4 THE WITNESS: I'd like to read it.

5 MS. GARCIA: And can I please
6 have -- just to make this clear on the
7 record, because we had a confusion about it
8 before, would you directly provide the
9 transcript to him?

10 THE COURT REPORTER: I will.

11 MS. GARCIA: Thank you.

12 And the address you provided, I
13 can't remember if you provided -- you did say
14 St. Paul. What's the zip code, just to make
15 it easy?

16 THE WITNESS: It's St. Paul.

17 MS. GARCIA: Okay. The zip code?

18 THE WITNESS: 1789 Summit Avenue.

19 MS. GARCIA: I'm sorry, the zip
20 code?

21 THE WITNESS: 55105.

22 MS. GARCIA: Thank you.

23 MR. SACCHET: Okay. Just give me
24 one second.

25 EXAMINATION

1 NACHTSHEIM

2 BY MR. SACCHET:

3 Q. Professor Nachtsheim, as I mentioned this
4 morning, my name is Michael Sacchet. I
5 represent the plaintiffs in this matter.

6 For the sake of just, you know,
7 laying out the ground rules once more to
8 mention, if I ask questions, please respond
9 verbally just as you did for Ms. Garcia. And
10 in the same vein, please let me answer -- or
11 ask the questions before you answer them as
12 well, okay?

13 A. (Nods head.)

14 Q. I'd like to turn back to the CV, which was
15 previously marked as Exhibit 3.

16 MS. GARCIA: Would you like me to
17 go get the updated one?

18 MR. SACCHET: No, that's fine.

19 MS. GARCIA: Okay. Before we
20 leave today we should probably go get that.

21 MR. SACCHET: Yeah.

22 MS. GARCIA: I'm sorry. I
23 apologize for interrupting.

24 MR. SACCHET: Yeah, no worries.

25 MS. GARCIA: I'll do that before

1 NACHTSHEIM

2 we sign-off.

3 MR. SACCHET: Yeah. We'll just
4 work off the --

5 MS. GARCIA: Okay.

6 MR. SACCHET: -- the one that you
7 were working off of.

8 BY MR. SACCHET:

9 Q. So from what I can tell in the document,
10 you've delineated your education,
11 professional experience, honors and awards,
12 elected offices, editorial awards, textbooks,
13 publications, courses taught and some
14 conferences you've presented; is that
15 correct?

16 A. Correct.

17 Q. Let's start at the top of the document with
18 respect to your education. If you wouldn't
19 mind just providing a quick background of
20 your BA, MS and Ph.D., please.

21 A. I received my bachelor's degree in
22 mathematics and quantitative methods at the
23 University of St. Thomas, college of
24 St. Thomas at that time. Went from there to
25 Rensselaer Polytechnic Institute for a

1 NACHTSHEIM

2 master's degree in -- in operations research
3 and statistics. Returned -- returned to
4 Minnesota, went to the University of
5 Minnesota where I did a Ph.D. in operations
6 research.

7 Q. What does the term operations -- operations
8 research exactly mean?

9 A. Operations research really means -- it's
10 really mathematics applied to operations
11 problems in -- usually in business, large
12 operations. It started in World War II with
13 logistics and so forth with regard to troops
14 and so forth, but it has to do with
15 optimizing business processes and so forth.

16 But much of the -- much of the
17 background that one gets in operations
18 research, for Ph.D.s in operations research,
19 can be very, very similar to what people get
20 in Ph.D.s in statistics.

21 And, in fact, most of my coursework,
22 because I already had a master's in
23 operations when I came, most of my coursework
24 was in the statistics department. And --
25 and, in fact, my thesis advisor is a

1 NACHTSHEIM

2 statistician and was in the stat -- was in
3 the statistics department.

4 Q. And your thesis advisor is Professor
5 Dennis Cook?

6 A. Correct.

7 Q. And your thesis was entitled, "Contributions
8 to Optimal Experimental Designs"?

9 A. Correct.

10 Q. What do you mean by the term, "Optimal
11 experimental designs"?

12 A. So when we design an experiment we want to
13 get as much information as we can with the
14 fewest number of observation possible. And
15 so we can actually formulate this as a
16 mathematical problem and -- and find an
17 optimal solution to the mathematical problem,
18 and that's called an optimal experimental
19 design.

20 Q. And after you graduated with your Ph.D. you
21 spent two or three years in the private
22 sector, correct?

23 A. I did. I first was in Los -- at Los Alamos
24 National Laboratory for three years in
25 the statistics group, and then went to

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2 General Mills.

3 Q. And from there you entered academia?

4 A. Yes.

5 Q. When did you receive tenure?

6 A. I received tenure, I believe it was 1988. Is
7 that right? I think I have it here.

8 (Reviews document.) Let's see, I came
9 in '84. Yeah, I believe it was 1988.

10 Q. It says it in the last line.

11 And you were appointed the Associate
12 Dean of Faculty and Research in 1996?

13 A. Nineteen ninety -- yes, 1996. I was
14 appointed Department Chair in '93 and then
15 Associate Dean of Faculty in '96.

16 Q. What were your responsibilities as the
17 Associate Dean of Faculty?

18 A. I was the COO of the business school. When
19 you're Associate Dean of Faculty, you're the
20 number two person in the business school, you
21 report to the Dean, and all of the faculty
22 report through the departments to you. I was
23 also in charge of information systems and
24 personnel and nearly everything.

25 The way it was set up, you basically

1 NACHTSHEIM

2 run the business school, the Dean is
3 responsible for raising funds and -- and
4 external relations and so forth.

5 Q. And how long were you in that position for?

6 A. I was in that for four years.

7 Q. Okay. And then what did you transition to?

8 A. So I transitioned to -- I had two years as a
9 regular faculty member, full professor, and
10 then I was asked to be department chair
11 again, and so I became department chair, I
12 did that for the next 12 years.

13 Q. And you were a department chair in operations
14 management?

15 A. It's called operations, and we changed names,
16 operations in management science, and the
17 name was changed to supply chain and
18 operations a few years ago.

19 Q. Okay. And I think we've established that
20 Exhibit 3 is not up to date. Are you still
21 in that position now or have you changed to
22 something new since 2011, 2012?

23 A. Oh, it's -- this has me as the -- as chair of
24 supply chain and operations, and I'm no
25 longer chair.

1 NACHTSHEIM

2 Q. Okay.

3 A. In 2014 I reverted to being a faculty member,
4 and also somewhere in there I became a
5 chaired professor. So those things would be
6 reflected in the -- in the new guide, the new
7 version of the resume.

8 Q. So for the past 20 years or so in academia,
9 it appears that you've received a number of
10 honors and awards, correct?

11 A. Correct.

12 Q. You've received the Brumbaugh Award three
13 times, at least?

14 A. Four times now. It's reflected in -- in the
15 new resume.

16 Q. What was that award given to in the most
17 recent year?

18 A. I believe it was 2015.

19 Q. Okay. And for what?

20 A. It's for the paper published in the area of
21 quality that has the biggest impact on -- no,
22 no, that's a different award. It's basically
23 the best paper published in the area of
24 quality.

25 Q. And by, "Quality," does that involve

1 NACHTSHEIM

2 statistics?

3 A. Yes, it does. Because we have things like
4 statistical process control and business
5 process -- or process improvement, these are
6 all heavily statistics.

7 Q. Would it be fair to say that you've earned at
8 least eight awards for publishing papers in
9 the field of statistics?

10 A. Yes.

11 Q. And you've also been elected as the fellow of
12 the American Statistical Association?

13 A. Yes.

14 Q. What do your responsibilities as a fellow
15 entail?

16 A. It's really an honor. It's -- I think it's
17 less than 1 percent of -- of professional
18 statisticians are elected as fellows.

19 Q. Do you view the other fellows in the
20 association as luminaries in the field?

21 A. I do.

22 MS. GARCIA: Object to the form of
23 that question.

24 BY MR. SACCHET:

25 Q. Do you -- do you view them as experts in the

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2 field?

3 A. I view them --

4 MS. GARCIA: Object to the form of
5 the question.

6 THE WITNESS: I -- I -- I view
7 them as experts in the field.

8 BY MR. SACCHET:

9 Q. And prior to that you were the chair of the
10 section on physical and engineering sciences
11 for the association, and then thereafter you
12 were the president of the Twin Cities
13 Chapter, correct?

14 A. Yes.

15 Q. Were you elected as the president of the
16 Twin Cities Chapter?

17 A. Yes, I was.

18 Q. How many people are in the Twin Cities
19 Chapter?

20 A. I -- I don't know, but I'm -- I'm going to --
21 I'm going to guess the number is probably
22 200, something like that.

23 Q. Is Professor Cook a member?

24 A. Yes.

25 Q. And Professor Cook is a nationally-known

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2 statistician?

3 A. Yes, he is a nationally -- he's a -- he's an
4 internationally known statistician.

5 Q. So at least one internationally-known
6 statistician, presumably, nominated you to
7 become president of the Twin Cities Chapter
8 of the American Statistical Association?

9 A. Yes. Well -- well, you know, frankly, I'm --
10 I don't know who nominated me and I don't
11 know how Dennis -- how Professor Cook voted,
12 so I can't really say anything about that,
13 but...

14 Q. You were elected by a body of people who were
15 all members?

16 A. But I was elected by a body of people,
17 correct.

18 Q. And you were also on various editorial
19 boards?

20 A. Yes.

21 Q. And some of those boards involve statistical
22 papers?

23 A. So it -- yes, those are all -- those are all
24 statistics journals, they're all top
25 statistics journals and it involves

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2 conducting peer review and making
3 recommendations about publications in those
4 journals.

5 Q. Is the American Statistician a preeminent
6 journal?

7 A. Yes, it is.

8 Q. And you receive papers every now and then to
9 evaluate and determine whether they should be
10 published or not?

11 A. Correct.

12 Q. And you've been doing that for at least five
13 years?

14 A. I've been doing -- yes, I've been doing that
15 off and on probably for 25 years.

16 Q. So you're well familiar with the peer review
17 process?

18 A. I am.

19 Q. And you've also published at least two
20 textbooks, potentially three, based on the
21 business statistics data driven
22 decision-making that was in progress at the
23 time this resume was --

24 A. And I've kind of -- that's been on the --
25 it's two-thirds completed and it's been on

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2 back burner because I've been so busy with
3 research, but the other two books. So
4 there's really just two books.

5 Q. Okay. And you've published at least 58 peer
6 reviewed articles, correct?

7 A. Yes.

8 Q. What percentage of these -- of those articles
9 would you determine to be related to
10 statistics?

11 MS. GARCIA: Object to the form of
12 the question.

13 THE WITNESS: So I -- I -- I --
14 I -- I -- I think probably 95 percent of them
15 are purely in statistics methodology, then
16 there are some application papers, and these
17 papers -- the papers, for example, Exhibits 4
18 and 5, are examples of applications papers
19 that are related to statistics, but are not
20 published in a statistics journal.

21 BY MR. SACCHET:

22 Q. What is your understanding of the peer review
23 process?

24 A. My -- the peer review -- my understanding of
25 the peer review process is that a paper is

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2 submitted to a journal, the journal editor
3 generally looks at it and decides whether it
4 is -- has a chance of being published, and --
5 and if not, rejects them out of hand.

6 If they -- if he feels -- he or she
7 feels that it's a -- has potential, it may
8 be -- it may be a rigorous, useful study,
9 it's either passed on to a board of -- in my
10 field, generally, it's an editorial board,
11 and he can -- and he or she can pick people
12 from the board and ask them to conduct a --
13 be referees of the paper, review the papers,
14 or it's handed off to an associate editor who
15 then brings in experts, and those experts are
16 always experts in the particular field
17 related to the paper, in the subfield related
18 to the paper.

19 Q. So there's at least one referee expert or
20 another individual, whatever their title may
21 be, that evaluates the paper and determines
22 whether it has met specific scientific
23 criteria in order to be published as a peer
24 reviewed publication?

25 A. Correct. Usually there's -- there's an

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2 editor review and associate editor review and
3 two -- two -- two referees, so there's
4 generally three or four reviews.

5 Q. And Exhibits 4 and 5, namely, the McGovern
6 article and the Belani article, went through
7 that process, correct?

8 A. Yes.

9 Q. And at least one independent person reviewed
10 those manuscripts and determined that they
11 were suitable to be published in the
12 respective journals?

13 A. Yes, they did go through -- they went through
14 the peer review process.

15 Q. You've also performed funded research before,
16 correct?

17 A. I've performed funded research, yes, some.

18 Q. And you've done some --

19 A. But I do want to make a distinction. My
20 colleagues in the statistics department or
21 industrial engineering departments do much --
22 or biostatistics do much, much more of this.
23 I happen to be in a business school where our
24 focus is -- we need to focus -- we focus on
25 teaching and much of our research is funded

1 NACHTSHEIM

2 by the school, so there's not -- there isn't
3 the same kind of expectation of -- of raising
4 external funds --

5 Q. Okay.

6 A. -- in a -- in a business -- that's standard
7 in -- in top business schools.

8 Q. And you have received funding from private
9 organizations and public, i.e., governmental
10 entities, correct?

11 A. Right. Yes, I have.

12 Q. And one of those private entities was 3M,
13 correct?

14 A. Well, I don't know that I did research for
15 3M. They -- they paid me to come and give
16 workshops, things of that nature, but I --
17 and I've done -- I've maybe done some
18 consulting. Is there something in particular
19 which you --

20 Q. Yeah. If you want to turn to page 9, there's
21 a 3M McKnight Foundation grant that was
22 awarded in 1987.

23 A. Ah, right. So 3M provides the funds, and the
24 McKnight Foundation awarded the -- the
25 research money, so it wasn't directly for 3M.

1 NACHTSHEIM

2 Q. Fair enough.

3 And you also have taught numerous
4 courses at both the University of Minnesota
5 and the Carlson School, correct?

6 A. Yes, I have.

7 Q. And the majority of those courses involved
8 statistics?

9 A. All of them involved statistics.

10 Q. And they also involve optimal design of the
11 experiments?

12 A. The doctoral courses that I teach in
13 experimental design involve optimal design.
14 I -- I -- I teach MBA classes and executive
15 MBA classes, and that's a little too
16 advanced.

17 Q. Okay.

18 A. So -- so I don't teach optimal design in
19 those, but I do teach some experimental
20 design at a simplified level and then all of
21 the other materials that go into a statistics
22 class for analyzing data and regression
23 analysis, things of that nature --

24 Q. And you've --

25 A. -- hypothesis testing, all that.

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2 Q. And you've taught at least ten different
3 classes involving statistics in your career
4 at the University of Minnesota?

5 A. Yes.

6 Q. And some of those classes involve
7 multivariate analysis?

8 A. Yes.

9 Q. And some of them involve univariate analysis?

10 A. Correct.

11 Q. Some of them touch on observational studies?

12 A. Yes.

13 Q. And some of them involve Poisson regression?

14 A. Yes. Let me be -- let me be careful about
15 Poisson -- yes, I have taught -- in my
16 regression class I have taught Poisson
17 regression, yes.

18 Q. Based on --

19 A. That's at a doctoral level. That's at a
20 doctoral level.

21 Q. Based on your experience as a professor, the
22 publications that you've contributed to the
23 textbooks that you've published, you've been
24 asked to serve as an expert witness in a
25 variety of matters, correct?

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2 A. Correct.

3 Q. And you've done so for a variety of different
4 clients whether they be defendants or
5 plaintiffs, correct?

6 A. Correct.

7 Q. And at no point in time had you received
8 compensation for that consulting, did that
9 taint your views as to the legitimacy or
10 truth of what you were testifying in those
11 cases, did it?

12 A. I'm not aware that it did.

13 Q. So I assume that there are some items on your
14 resume, current resume that are not reflected
15 in this version that we've been discussing,
16 and I'd like to touch on those a little bit.
17 You wrote and contributed to an article that
18 was published in Technometrics, correct,
19 entitled, "Optimal Design for Engineering
20 Dimensional Analysis"?

21 A. Yes, I did. Yes.

22 Q. The paper was nominated and both selected to
23 be a discussion paper?

24 A. It was.

25 Q. Had you, prior to that time, ever been

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2 awarded that designation for publishing --

3 A. Yes, I had, a couple -- probably two or three
4 times.

5 Q. Okay. What does it mean to have a discussion
6 paper?

7 A. For that particular paper, the editor looked
8 at -- the editor tends to look at the papers
9 that have been published within the last year
10 and selects one of the top maybe two or three
11 papers and asks that paper to -- asks that --
12 those authors to present the paper in
13 what's -- in a -- in a special session at the
14 national conference.

15 Q. The national conference of statisticians?

16 A. Yeah.

17 Q. So the Technometrics article entitled,
18 "Experimental Design for Engineering
19 Dimensional Analysis," was a statistical
20 paper?

21 A. Yes, it is.

22 Q. And by being asked to present it as a
23 discussion paper, it presumably had notable
24 impact on the field, correct?

25 A. Yes.

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2 Q. And were there members of the panel whom
3 discussed the paper with you at that national
4 convention on statistics?

5 A. Yes.

6 Q. Who were those members?

7 A. There were three -- I think there -- I
8 believe there were three or four other
9 statisticians globally famous in the area of
10 experimental design. There was one from
11 England, Professor Jeff Wu from Georgia Tech.
12 There are a couple others, but they're all
13 very big names. They're all --

14 Q. Was the discussion well-received?

15 A. It was very well-received. And by the way,
16 that paper, and I just checked on this about
17 a month ago, that paper won the -- first of
18 all, won something called the Youden --

19 Q. Yeah, I'm going there.

20 A. Oh, you're getting there.

21 Q. But go ahead.

22 A. It's also -- it's also the most downloaded
23 paper in the history of Technometrics. It's
24 still number one in terms of the most
25 downloaded.

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2 Q. And Mark Albrecht was a coauthor of that
3 study, correct?

4 A. Correct.

5 Q. And he was similarly entitled to receive the
6 discussion paper nomination that you had
7 received?

8 MS. GARCIA: Object to the form of
9 the question.

10 THE WITNESS: He -- we received it
11 together.

12 BY MR. SACCHET:

13 Q. And as you mentioned, the paper was selected
14 to receive the Youden award, correct?

15 A. Yes, it received the -- the Youden prize,
16 which is given for the best paper in
17 Technometrics that year. And by the way, I
18 should mention, this was his master's thesis.

19 Q. Yeah.

20 A. Okay.

21 MS. GARCIA: Can we pause? Are
22 you going to ask more questions about the
23 updated CV? Because if you are, I'd really
24 like to go get it so I have it in front of
25 me.

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2 MR. SACCHET: No, I'm -- I'm
3 basically moving on right now.

4 MS. GARCIA: Okay.

5 MR. SACCHET: I've got about two
6 more questions on -- on -- on the CV.

7 MS. GARCIA: Okay. Do you have it
8 in front of you?

9 MR. SACCHET: The updated CV?

10 MS. GARCIA: Yes.

11 MR. SACCHET: I do not.

12 MS. GARCIA: Okay.

13 MR. SACCHET: I've just read the
14 documents and found out that all these awards
15 occurred in the time period in which --

16 MS. GARCIA: Thank you.

17 MR. SACCHET: Yeah.

18 BY MR. SACCHET:

19 Q. You were also asked to be a guest speaker at
20 the 2013 Randy Sitter Techno -- Technometrics
21 conference, were you not?

22 A. I was.

23 Q. What types of individuals give that
24 presentation on a yearly basis?

25 A. Well, if you're asked to -- to speak at a

1 NACHTSHEIM

2 conference of that level, you have to have a
3 fairly wide reputation as an active
4 contributor to current research.

5 Q. Based on the honors you've received, the
6 awards that you've received on your
7 publications, would you consider yourself an
8 expert in statistics?

9 A. Yes.

10 Q. What about experimental design?

11 A. Yes.

12 Q. Third parties recognize you, similarly, to be
13 expert in statistics, correct?

14 A. Yes.

15 Q. The Carlson School holds you out to be an
16 expert in statistics?

17 A. Yes.

18 Q. The Carlson School holds you out to be an
19 expert in experimental design, regression
20 analysis, and analysis of variance, quality
21 improvement methods, data mining and
22 predictive modeling; isn't that true?

23 A. This is true.

24 MS. GARCIA: Object to the form of
25 the question.

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2 THE WITNESS: Yes, it's true.

3 BY MR. SACCHET:

4 Q. And a newspaper or news source called,
5 The Motley Fool, recently interviewed you
6 to opine on data regarding Tesla --
7 Tesla Motors, correct?

8 A. Yes.

9 Q. And do you know whether in that article you
10 were named an expert in the design of
11 experiments?

12 A. I believe I was.

13 Q. Did you know that 3M has recently sought out
14 your expertise in terms of design and
15 statistics-related issues?

16 MS. GARCIA: Object to the form of
17 the question.

18 THE WITNESS: They have asked me
19 to give -- yes, they have. Yes, they have
20 recently in a -- in a couple of different
21 forms.

22 (Whereupon, Exhibit 25 was
23 marked for identification.)

24 BY MR. SACCHET:

25 Q. Do you see at the top of the document there

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2 is an e-mail from a woman named Jennifer Yi?

3 A. I do.

4 Q. Based on the document, can you see that
5 Jennifer Yi is a senior technical manager of
6 the patient-warming infection prevention
7 division of 3M?

8 A. I do.

9 Q. Can you see that Jennifer Yi wrote an e-mail
10 to an individual named Al Van Duren along
11 with numerous other individuals on 4/30/2015
12 at 6:10 p.m.?

13 A. Six -- oh, in the middle, 6 -- oh, wait a
14 minute.

15 Q. At the top.

16 A. At the top, sorry. Sorry, I jumped down.
17 Okay. Yes, I see that.

18 Q. And the subject line is forwarding an e-mail
19 entitled, "Statistical Practitioners Forum
20 Advanced DOE Class."

21 A. Yes, I see that.

22 Q. And below that e-mail do you see an e-mail
23 from a Jennifer Zoller?

24 A. I do.

25 Q. And it is sent to US-IP Lab, correct?

1 NACHTSHEIM

2 A. Yes. US-IP Lab, yes.

3 Q. And the text of the e-mail states -- of that
4 e-mail states, "Mike Besser highly recommends
5 this web stream and associated class, Jen";
6 do you see that?

7 A. Yes.

8 Q. And the e-mail below that is an e-mail from
9 Mike Besser, correct?

10 A. Yes, it is.

11 Q. Same subject title, "Statistical
12 Practitioners Forum Advanced DOE Class,"
13 correct?

14 A. Yes.

15 Q. And Mr. Besser states, "I'm not sure if
16 anyone attended the Intro on Definitive
17 Screening Designs. I've listened to the
18 recording link below and found this to be a
19 very intriguing and practical concept that
20 our stats practitioners may find useful.
21 There's a follow-up two-day course exclusive
22 to 3M'ers per Stu's attached e-mail"; do you
23 see that as well?

24 A. Yes.

25 Q. And below that there's a link?

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2 A. Yes.

3 Q. If you turn the page, there's an e-mail from
4 Stuart Janis, who is mentioned in the prior
5 e-mail?

6 A. Yes.

7 Q. And that e-mail states, "The statistical
8 practitioners forum and the tech forum
9 product design and development chapter are
10 hosting a class on advanced DOA covering
11 definitive screening designs, custom designs
12 and split plot designs for hard to change
13 factors. This class will be taught by
14 Professor Chris Nachtsheim." Do you see
15 that?

16 A. I do.

17 MS. GARCIA: Object. It also
18 says, "And Brad Jones."

19 MR. SACCHET: That is correct.
20 Noted.

21 BY MR. SACCHET:

22 Q. And on the final page bearing Bates number
23 3MBH01293499 --

24 A. Uh-huh.

25 Q. -- under, "Instructors," it notes, "Brad

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2 Johnson and Chris Nachtsheim are globally
3 recognized experts in the optimal design of
4 experiments and the inventors of definitive
5 screening designs. Together they were
6 recipients of the 2009 Brumbaugh award and
7 the 2009 Lloyd Ellis Nelson award of the
8 American Society for Quality for their paper
9 "Split Plot Designs"; do you see that?

10 A. Yes.

11 Q. Were you aware that 3M was distributing your
12 webcast to its employees among whom were
13 members of the IP lab in order to presumably
14 learn from your instruction about the proper
15 design of experiments?

16 A. I know that we had given them permission to
17 do that, so I -- I -- I thought they might do
18 it. I wasn't aware.

19 Q. Were you surprised earlier this afternoon
20 when you were questioned about your
21 contributions to the Belani and McGovern
22 paper given the fact that the same company is
23 recommending your expertise elsewhere?

24 MS. GARCIA: Object to the form of
25 the question.

1 NACHTSHEIM

2 THE WITNESS: I wasn't surprised.

3 MR. SACCHET: Fair enough.

4 BY MR. SACCHET:

5 Q. I'd like to turn now away from your resume
6 and towards your relationship with
7 Mr. Albrecht, who I may occasionally refer to
8 as Mark, but if I do, excuse me.

9 Approximately when did you meet
10 Mr. Albrecht?

11 A. I think it's been about -- I think it was
12 early 2000s. I think it's probably been
13 maybe 13 years ago. I'm not positive about
14 that, but I think it was right around then.

15 Q. In what capacity did you first meet him?

16 A. Mark -- I can refer him as Mark?

17 Q. Yeah, sure.

18 A. Mark was the -- was a student in our MBA
19 program and had taken the design of
20 experiments class from my colleague
21 William Lee, and Mark got very, very
22 interested in it and wanted to learn -- he
23 wanted to learn advanced marketing research
24 techniques, and there was no opportunity to
25 do that in the MBA program.

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2 And so he came to us and said, "I
3 would like to learn more about this, could we
4 work together and perhaps I can do this as an
5 independent study," with both Professor
6 William Lee and with me, and so we began
7 working -- we put together a study group and
8 it also involved one practitioner, a person
9 who owns a marketing research company, and we
10 met weekly for, I think, a couple of years.

11 And a couple of papers came out of
12 that. One didn't get published yet. We kind
13 of forgot about it. But another one was
14 published with Mark in this area, it's
15 called, Conjoint Analysis, and -- so that
16 was -- that was the -- that was how I first
17 began to work with Mark.

18 I think nearly half of his MBA
19 program was independent study with me, which
20 was -- so we did a lot of work, you know.
21 Then we tried to talk him into getting a
22 Ph.D., and we failed at that, but he decided
23 he wanted to get a master's degree in
24 statistics, and so he wanted to have me as
25 his advisor for that.

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2 Q. Let me back up just a moment. So when
3 Mr. Albrecht was in the MBA program, would it
4 be fair to say that he took courses or
5 received instruction that were more at a
6 Ph.D. level?

7 A. Yes.

8 Q. Would you agree that he quickly came up to
9 doing doctoral level work even though he was
10 only an MBA?

11 A. I would agree with that, absolutely.

12 Q. And while he was an MBA student, both you and
13 Mr. Albrecht coauthored at least one paper
14 that was peer reviewed in the scientific
15 literature?

16 A. Yes.

17 Q. And during that time did you work on the
18 forced-air warming papers?

19 MS. GARCIA: Objection; asked and
20 answered.

21 THE WITNESS: That was later.
22 That was -- that -- that -- that came later.
23 I believe Mark -- well, he certainly wasn't
24 in the MBA program anymore at the time, I
25 don't believe, that we did the -- that we

1 NACHTSHEIM

2 were working on the forced air.

3 That was -- do you know when he got
4 his P -- his master's degree? Well, he had
5 to -- well, wait a minute, I know, we
6 published that paper in 2011, so he was
7 pretty well through with his master's
8 probably in 2010.

9 So by -- by 2010, I'm not sure about
10 the Pure Air work, he may still have been
11 working on his master's degree at that time.

12 MR. SACCHET: Okay.

13 BY MR. SACCHET:

14 Q. And you mentioned the conjoint paper?

15 A. Yes.

16 Q. Was that submitted to Technometrics?

17 A. No, we submitted that to the Journal of
18 Quality Technology.

19 Q. Okay. But the dimensional analysis paper was
20 published in Technometrics when Mark Albrecht
21 was your master's in statistics student?

22 A. Correct.

23 Q. Okay. And we've established that he was a
24 coauthor on the paper, but what was his
25 contribution to the paper?

1 NACHTSHEIM

2 A. First of all, it was kind of interesting that
3 the -- the idea came, in part, because of a
4 problem that his brother Tom had working
5 at -- was he at Medtronic at the time, I'm
6 not -- I think he was at Boston Scientific at
7 the time. And so we went out to visit him to
8 talk about the problem, and then we realized
9 there was a very, very important problem that
10 hadn't been addressed in the literature, this
11 whole problem of how do you design an
12 experiment for something -- for something
13 called engineering dimensional analysis. And
14 I asked Mark to do a literature review, and
15 he did and he came up with nothing. And I
16 said, Wow, this is -- this is an amazing -- I
17 just can't believe no one has tackled this
18 area, and so we wrote that paper. And so
19 what was -- I would say -- I mean, Mark and I
20 worked -- Mark did all the hard work, did the
21 programming, did a lot of writing, it was his
22 master's paper. I certainly was heavily
23 involved in the direction of the research
24 and -- and -- and kind of teaching him about
25 some of the -- some of the stuff as we went

1 NACHTSHEIM

2 along.

3 Q. So Mr. Albrecht's master's paper was the same
4 paper that was the DA paper published in
5 Technometrics?

6 A. Yes.

7 Q. And that was the paper that both you and
8 Mr. Albrecht received the Youden award for?

9 A. Yes.

10 Q. And the Youden award is the best expository
11 paper that was published in Technometrics in
12 that year?

13 A. That's correct.

14 Q. Would that be a major honor for a tenured
15 faculty member to receive --

16 A. A major -- a major honor for a tenured
17 faculty member.

18 Q. Had you ever received it before?

19 A. Yes, I had received it -- I'm trying to get
20 my years correct here. I believe I had
21 received it once before.

22 Q. Would it be unusual --

23 A. In fact, only recent.

24 Q. Would it be unusual for a graduate student to
25 be awarded the Youden award?

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2 A. It's unheard of. And -- and, in fact, the
3 statistics department made a very, very big
4 deal out of it and had a -- on their website
5 they made a big showing of Mark having won
6 the Youden prize for his master's paper.

7 Q. Isn't it true that Professor Dennis Cook, who
8 is your mentor and advised your thesis paper
9 when you received a Ph.D., was the individual
10 who recommended that Mr. Albrecht be
11 publicized on the Carlson School's website?

12 A. I think that's -- yes, it is, that's correct.

13 Q. And Mr. Cook, as you mentioned, is a
14 nationally, if not internationally, known
15 statistician, correct?

16 A. He's an internationally-known statistician.

17 Q. Was this Mr. Albrecht's first peer stats
18 paper?

19 A. Yes, I think this was his first peer stats
20 paper. There was a lot of statistics in the
21 conjoint paper that we published in the
22 Journal of Quality Technology, and the other
23 paper was pretty much pure statistics that we
24 wrote when he was a master's degree that we
25 never published.

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2 Q. Okay. So to pull it all together,
3 Mr. Albrecht's first peer stats paper was the
4 same paper that he received an honor which
5 would be noteworthy for a tenured faculty
6 member to receive, but he received when he
7 was a graduate student, right?

8 A. Correct.

9 MS. GARCIA: Object to the form of
10 the question.

11 BY MR. SACCHET:

12 Q. When Mr. Albrecht graduated from the master's
13 and statistics program, did he earn a 4.0?

14 A. I think he -- I believe he did. I -- as far
15 as I know he did.

16 Q. Based on your recollection, did Mr. Albrecht
17 publish more original statistics research
18 than most of your Ph.D. students would during
19 their five years of study?

20 A. Yes.

21 Q. After Mr. Albrecht graduated with his MBA and
22 MS in statistics, did you ever seek
23 Mr. Albrecht's assistance as to your work?

24 A. I'll tell you what, the paper on -- the
25 earlier paper that we -- we sent to the

1 NACHTSHEIM

2 Journal of Quality Technology, I was working
3 with my colleague, William Lee, who was also
4 a fellow of the American Statistical
5 Association, and I felt that the draft we had
6 didn't go deep enough in certain areas. And
7 apparently William and I didn't have time
8 to -- to do that and we weren't getting this
9 paper done, so I called -- I asked -- I said
10 to William, "I think we need to bring Mark
11 in, because Mark can do a good job on this
12 for us," and so William agreed and we brought
13 Mark in as part of the team and Mark wrote
14 the last, I would say, one-third of the paper
15 and did the methodology, so, yes.

16 Q. And that paper involved statistics?

17 A. Absolutely.

18 Q. Did you ever ask Mr. Albrecht how it would be
19 best to teach MBA statistics from a --

20 A. Yes, I have.

21 Q. -- pedagogical perspective?

22 A. Yes, I have.

23 MS. GARCIA: I'm sorry, I didn't
24 hear the end of your question.

25 MR. SACCHET: From a pedagogical

1 NACHTSHEIM

2 perspective.

3 MS. GARCIA: Thank you.

4 BY MR. SACCHET:

5 Q. Did you ever ask Mr. Albrecht to edit any of
6 the textbooks that were pending publication?

7 A. You know, I very well may have. They were
8 last published in 2005 and 2006. You know, I
9 can't remember doing that, but I wouldn't be
10 a bit surprised if I had, because we were
11 working so closely together that -- at that
12 time that I very well may have.

13 Q. Do you recall in about February 2012 asking
14 Mr. Albrecht to mark up book chapters,
15 perhaps it wasn't related to a textbook?

16 A. I don't recall that. I -- but that was when
17 I was writing the textbook for -- for
18 statistics, so I -- it certainly -- I would
19 do that, it wouldn't surprise me a bit,
20 because I -- he had a master's -- he had done
21 the MBA, this is a book aimed at MBAs. I
22 wouldn't be surprised. I just -- I'm trying
23 to remember. I just don't remember doing it.

24 Q. Given Mr. Albrecht's performance as one of
25 your MBA students and MS students and the

1 NACHTSHEIM

2 honors that he received while he was your
3 student, you hold Mr. Albrecht in high
4 regard?

5 A. I -- I hold him in very, very high regard.
6 He's by far the smartest, the best student I
7 have ever had in my life and I am continually
8 impressed with what he accomplishes not just
9 in the publishing realm or in the writing
10 realm, but in his business endeavors.

11 Q. And, in fact, when Mr. Albrecht applied to
12 the national marrow donors program, you
13 informed the hiring person there that
14 Mr. Albrecht was without question the best MS
15 student, i.e. master's in statistics, student
16 with whom you've ever had the opportunity to
17 work with, correct?

18 A. Absolutely.

19 Q. You've also told your colleagues such as
20 Professor Dennis Lynn that Mr. Albrecht is a
21 genius?

22 A. I -- I don't know if I used the word genius,
23 but -- but I certainly said that he's very,
24 very bright, absolutely.

25 Q. Did Mr. Albrecht win the 2013 MFESTS Young

1 NACHTSHEIM

2 Science and Technology Professional of the
3 Year award?

4 A. Yes, he did.

5 Q. Who generally receives that award?

6 A. Only the very best young engineers.

7 Q. And did Mr. Albrecht's contribution to the
8 field of statistics have anything to do with
9 winning the award?

10 A. It did.

11 MS. GARCIA: Object to the form
12 and foundation for that question.

13 BY MR. SACCHET:

14 Q. On what grounds?

15 MS. GARCIA: Object to the form
16 and foundation for that question.

17 THE WITNESS: I nominated him for
18 that, for that award, and so part of what was
19 I think -- I thought compelling at the time
20 was his master's thesis and the other paper
21 that he had already published. So in
22 addition -- in addition to some of the
23 purely -- pure engineering things he had been
24 doing, I think by that time he had already
25 run the clinical trial -- I mean, he -- he

1 NACHTSHEIM

2 had done some of the work on these papers and
3 so as an accomplished engineer who was also
4 publishing in statistics journals and -- do
5 you happen to have what year that was that he
6 won the --

7 MR. SACCHET: Yeah. Well,
8 you recommended him in November -- on
9 November 28th, 2012.

10 THE WITNESS: Yeah, so he had
11 already -- he had been publishing in medical
12 journals and statistics journals and doing
13 engineering and so forth, so...

14 BY MR. SACCHET:

15 Q. And some of those publications were the
16 McGovern paper and the Belani paper, i.e.,
17 Exhibits 4 and 5 that we've discussed today,
18 correct?

19 A. Correct.

20 Q. Based on those publications and the other
21 work that Mr. Albrecht did, would you
22 consider Mr. Albrecht an expert in
23 statistics?

24 A. Yes, absolutely.

25 Q. You have referred to Mr. Albrecht as an

1 NACHTSHEIM

2 expert in regression, correct?

3 A. Yes.

4 MS. GARCIA: Object to the form of
5 the question.

6 BY MR. SACCHET:

7 Q. You have referred to Mr. Albrecht as an
8 expert in multivariate dimensional analysis,
9 correct?

10 A. Correct.

11 MS. GARCIA: Object to the form of
12 the question.

13 BY MR. SACCHET:

14 Q. At the time that Mr. Albrecht coauthored the
15 McGovern and Belani studies, he was there for
16 an expert in the statistical methods,
17 correct?

18 A. Yes.

19 MS. GARCIA: Object to the form of
20 the question.

21 BY MR. SACCHET:

22 Q. You had no reason to doubt Mr. Albrecht's
23 skills in the field of statistics, do you?

24 A. I have no reason to doubt his skills in
25 statistics.

1 NACHTSHEIM

2 Q. You have no reason to doubt his credibility
3 in publishing scientific literature, do you?

4 A. I do not.

5 Q. You have all the confidence that you could
6 have that Mr. Albrecht did his homework and
7 reviewed the data and published through
8 accurate results in both the McGovern and
9 Belani papers, correct?

10 MS. GARCIA: Object to the form of
11 the question.

12 THE WITNESS: I absolutely do.

13 BY MR. SACCHET:

14 Q. After Mr. Albrecht graduated from the
15 Carlson School, where did he seek employment?

16 A. So his -- I don't know what you mean by,
17 "Seek." I know that he -- he went to -- he
18 went to be the match -- the National Marrow
19 Donor Program. I think that was his first
20 job after getting his master's degree and
21 having worked at Augustine Biomedical.

22 Q. Do you know whether Mr. Albrecht ever applied
23 to work at 3M?

24 A. Yes, he did.

25 Q. Do you know whether 3M accepted his

1 NACHTSHEIM

2 application? Or I guess I should
3 rearticulate the question to say do you know
4 whether Mr. -- or 3M offered Mr. Albrecht the
5 position at 3M?

6 A. Yes, they did. Now I remember. Yes, they
7 offered him a position.

8 Q. Do you know what position Mr. Albrecht
9 applied for?

10 A. Well, it was -- I believe it was a statistics
11 position.

12 Q. Do you know whether Mr. Albrecht accepted the
13 position in statistics at 3M?

14 A. Yes, he did. He did, he accepted it.

15 Q. Do you know whether Mr. Albrecht worked at 3M
16 in that statistics position?

17 A. I don't believe he worked -- I don't remember
18 whether he worked in it. I know that they
19 determined that they had to renig on the
20 offer they made him for legal reasons, so
21 I -- I don't -- I don't think he had -- he
22 may have started there, I just don't -- I
23 don't remember the details.

24 Q. Were you surprised that a company like 3M
25 would offer Mr. Albrecht a position in their

1 NACHTSHEIM

2 statistics department?

3 A. Not a bit.

4 Q. Why?

5 MS. GARCIA: Let me object to the
6 form of that question.

7 THE WITNESS: Well, first of all,
8 they called me, they had an opening and they
9 called me to ask me if I had anyone that I
10 could recommend for them for that position.
11 And, in fact, it might have even been
12 Stu Janis, who was in one of the e-mails you
13 mentioned earlier.

14 And I said, "I have somebody who is
15 absolutely perfect for you, but I think
16 you're too late," because I think by that
17 time he was about to accept a position maybe
18 at the Donor Marrow Program, I don't know,
19 but they had kind of gone through the --
20 through the interview process.

21 And he had -- Stu had just described
22 to me the -- the search procedure they were
23 going to go through and it was -- it was
24 going to take, you know, another couple of
25 months. I think they were going to do kind

1 NACHTSHEIM

2 of a national search, I guess, I don't know.

3 I said, "I think you would have
4 about ten days to decide on this person," and
5 I said, "If I were you, I would have him out
6 tomorrow for an interview and -- and do
7 things differently than you usually do them,
8 make a quick decision."

9 And I think that was on a Monday or
10 a Tuesday. That Friday they had Mark -- I
11 think it was Friday, Thursday or Friday, they
12 had Mark out for an interview and Monday they
13 had a job offer for him.

14 BY MR. SACCHET:

15 Q. Have you been deposed before?

16 A. Yes.

17 Q. Have you ever been deposed by a company who
18 offered you a job but later deposed your
19 ability to accurately perform the
20 responsibilities that you were offered a job
21 for?

22 A. No.

23 MS. GARCIA: Object to the form of
24 the question. That misstates the record in
25 multiple ways.

1 NACHTSHEIM

2 THE WITNESS: That's never

3 happened to me.

4 BY MR. SACCHET:

5 Q. I'd like to turn to the McGovern study, which
6 was marked as Exhibit 4. The study involved
7 two components, an experimental part and an
8 observational data component, correct?

9 A. Correct.

10 Q. And you previously testified that you had no
11 role in the design or setup as to the
12 experimental portion of the study, correct?

13 MS. GARCIA: Objection to the
14 extent that you're going to go through
15 questioning that we've been through all day,
16 asked and answered.

17 BY MR. SACCHET:

18 Q. You can answer the question.

19 A. Oh, which? This is Belani?

20 Q. No, McGovern.

21 A. It's McGovern, okay. Yeah, I did -- I did
22 not have a direct input to the design of that
23 study, and I'm just talking about the 3 by 2
24 experiment and two replicates.

25 Q. You were involved in the statistical --

1 NACHTSHEIM

2 A. Although, I may maybe have merged the two
3 replicates, I'm not sure.

4 Q. You were involved in the statistical analysis
5 portion of the study, correct?

6 A. I was.

7 Q. If you could turn to page 1540 of the study.

8 A. (Complies.)

9 Q. On the bottom left-hand column it states, "A
10 Poisson regression model was fitted to the
11 hip replacement data having the sum of bubble
12 counts for each experimental run," parens,
13 "Five photographs," end parens, "As the
14 response and the factors identified in the
15 experimental design as predictors"; is that
16 what it says?

17 A. Yes, it does.

18 Q. And above that paragraph there are two
19 figures, Figures 4 and Figure 5, correct?

20 A. Correct.

21 Q. In both figures, whether it's a pure bubble
22 count or a sum bubble count, there were
23 largely zero values for bubbles produced from
24 conductive fabric warming, correct?

25 A. Correct.

1 NACHTSHEIM

2 Q. The fact that there were numerous zero values
3 within the data set meant that it would be
4 most proper to perform a Poisson regression,
5 correct?

6 A. I think the -- the existence of zeros isn't
7 what does it, it's the existence of counts.
8 Zeros are fine.

9 Q. Would the fact --

10 A. Having zeros does not -- is totally -- is
11 appropriate --

12 Q. Okay.

13 A. -- when doing a Poisson regression.

14 Q. Does the fact that photographs were taken in
15 even increments further justify the use of a
16 Poisson regression?

17 MS. GARCIA: Object to the form of
18 the question.

19 THE WITNESS: I think it -- I
20 think it's perfectly -- I think it justifies
21 the use of Poisson regression, yes.

22 BY MR. SACCHET:

23 Q. And the use of a Poisson regression made more
24 sense than using a full ANOVA model, correct?

25 A. Correct. And -- and if I may, ANOVA is just

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2 a special case of regression, so one could
3 also say standard regression versus Poisson
4 regression.

5 Q. Okay. Thanks for the clarification.

6 A. But yes.

7 Q. If we can look at the, Results, section on
8 the same page, the first sentence states,
9 "Bubble counts per photograph show that
10 forced-air warming mobilized under drape air
11 so that it passed over the anesthesia surgery
12 drape and into the surgical site," parens,
13 "Figure 4," end parens, "But conductive
14 fabric did not have a mobilizing effect"; do
15 you see that?

16 A. I do.

17 Q. It then says, "Based upon Wald tests,
18 differences in the sum of bubble counts for
19 each experimental run," parens, "Figure 5,"
20 end parens, "Were significant between
21 conductive fabric and forced-air warming for
22 the drape configuration of half drape,"
23 parens, "0 versus 68 with a p-value of less
24 than .001," end parens, "And laid down,"
25 parens, "0 versus 3 p-value of .01," end

1 NACHTSHEIM

2 parens; do you see that?

3 A. I do.

4 MS. GARCIA: And object that the
5 remainder of the sentence says, "Differences
6 for full drape," paren, "0 versus 1 P
7 equals .283," close paren, "Did not reach
8 statistical significance"; is that also
9 correct?

10 THE WITNESS: Yes.

11 MS. GARCIA: Thank you.

12 BY MR. SACCHET:

13 Q. What does the p-value with respect to the
14 draping at half height and laid down suggest
15 or mean?

16 A. So it suggests that the difference in counts
17 for the conductive fabric and forced-air
18 warming are not due to chance.

19 Q. And by not being due to chance, that means
20 that they are statistically significant --

21 A. That's means, they -- yes, they are
22 statistically significant. The differences
23 that are observed from those two conditions
24 is a statistically significant difference.

25 Q. And so if you employed this same experiment

1 NACHTSHEIM

2 numerous times over, you would very likely
3 generate the same significant data --

4 A. Yes.

5 Q. -- as to the bubble counts?

6 A. Yes.

7 MS. GARCIA: Object to the form of
8 the question.

9 BY MR. SACCHET:

10 Q. You submitted this paper to the Journal of
11 Bone and Joint Surgery, correct?

12 A. Yes.

13 Q. And when you submitted it to that journal, it
14 went through the peer review process,
15 correct?

16 A. Yes, it did.

17 MS. GARCIA: I just object for
18 clarity. Do you mean he personally submitted
19 it?

20 BY MR. SACCHET:

21 Q. Your team, the coauthors of this paper
22 submitted this paper to the journal, correct?

23 A. The paper was submitted and it went through
24 the peer review process.

25 Q. And you testified earlier that as part of the

1 NACHTSHEIM

2 peer review process, there is always at least
3 one independent reviewer who reviews the
4 manuscript and determines whether it's worthy
5 of publication?

6 A. Correct.

7 Q. And this paper was, in fact, determined to be
8 worthy of publication in this journal,
9 correct?

10 A. Correct.

11 Q. Do you continue to stand by the results of
12 the bubble count data that is presented in
13 this study?

14 A. I do.

15 Q. Do you have any doubts as to the statistical
16 analysis that was performed as to the bubble
17 count data?

18 A. I have no doubts.

19 Q. Do you continue to stand by the conclusion
20 that the increase in bubble counts may be a
21 proxy for demonstrating increased bacteria at
22 the surgical site caused by the Bair Hugger?

23 MS. GARCIA: Object to the form of
24 the question.

25 THE WITNESS: I think the -- the

1 NACHTSHEIM

2 increase in bubble counts suggests there's a
3 potential for particles coming from lower up
4 over and into the -- the -- or the -- what do
5 you call it, the incision spot. It shows
6 that there are airflows that can lead
7 particles into those sites, and I -- from
8 what I understand, some of those particles
9 could be bacteria.

10 BY MR. SACCHET:

11 Q. The fact that only two runs of each factor
12 were performed did not pose a statistical
13 issue, because the null hypothesis was
14 ultimately rejected, correct?

15 A. Right. Yes, the -- the -- the fact that
16 the -- the effect was so powerful, we only
17 required two replicates of the experiment.

18 Q. And by, "So powerful," you mean that the
19 p-value was so significant for this data set
20 that you -- there was no point in performing
21 additional runs?

22 A. Right. And -- and really what I mean by that
23 is the effect of changing from one -- from
24 one blanket to the other was large enough
25 such that you can -- you can prove it's not

1 NACHTSHEIM

2 due to chance with just two replicates, and
3 that's not at all common in well-designed
4 experiments.

5 Q. So you would consider this to be a
6 well-designed experiment?

7 A. Yes.

8 Q. In the context of the Belani study, you
9 mentioned that certain variables were not
10 analyzed in this type of experimental setup,
11 correct, such as the lighting, surgical
12 tools, surgeons in the room and things of
13 that nature, correct?

14 A. Correct.

15 Q. Is it your understanding that the presence of
16 those types of obstacles could either disrupt
17 the laminar flow to a greater degree or
18 potentially reduce it, but you have no view
19 one way or the other as to the effect?

20 A. Yes.

21 Q. So it's possible that if those obstacles had
22 been presented in the McGovern study, that
23 the results would even be more powerful?

24 MS. GARCIA: Object --

25 THE WITNESS: It's possible.

1 NACHTSHEIM

2 MS. GARCIA: Object to the form of
3 the question.

4 BY MR. SACCHET:

5 Q. Let's take a look at the observational
6 component of the study.

7 MS. GARCIA: Which study?

8 MR. SACCHET: Of the McGovern
9 study, Exhibit 3.

10 MS. GARCIA: Exhibit 4.

11 MR. SACCHET: Four, excuse me.

12 THE WITNESS: (Complies.)

13 BY MR. SACCHET:

14 Q. If we could turn to page 1541, would you
15 agree that the final data set involved 1,437
16 patients?

17 A. Yes.

18 Q. And if you turn back a page to -- actually,
19 one page over to 1542, viewing table 2, would
20 you agree that 371 of those patients received
21 conductive fabric warming, whereas, 1,066 of
22 those patients received forced-air warming?

23 A. This is in table 2?

24 Q. Yes. You'll need to add the -- those
25 developing an infection with those not

1 NACHTSHEIM

2 developing an infection.

3 A. Ah. (Reviews document.) Okay. And what
4 were your numbers again?

5 Q. Three out of 371 patients -- oh, actually, I
6 should backtrack. Three hundred and
7 seventy-one patients received conductive
8 fabric warming, whereas 1,066 received
9 forced-air warming, correct?

10 A. I'm -- I'm being dense here, because I'm not
11 seeing --

12 Q. Yeah, let me help you out. So in table 2 --

13 A. Yeah, please do.

14 Q. -- if you go about almost to the bottom of
15 the table, there is a header that says,
16 "Patient-warming device" --

17 A. Right.

18 Q. -- with number and then percent, "Conductive
19 fabric," there's a 3, which presumably is the
20 N, i.e., the sample, correct?

21 A. Right, that developed the infections, right.

22 Q. Yeah. And then in the next column over is
23 368, which stands for those who did not
24 develop an infection, correct?

25 A. Correct.

1 NACHTSHEIM

2 Q. So the total patient population for those
3 received conductive fabric warming was 371,
4 correct?

5 A. Now I get it.

6 Q. Yeah. I probably shouldn't move so fast, but
7 now that we're together, that's good.

8 A. Yeah, good.

9 Q. And for forced-air warming, I guess I'll just
10 jump to it, 1,066, correct?

11 A. Correct.

12 Q. Okay. And from those patient populations, 3
13 out of the 371 who received conductive fabric
14 warming developed an infection?

15 A. Correct.

16 Q. While 32 out of the 1,066 who had forced-air
17 warming developed an infection, correct?

18 A. Correct.

19 Q. And the differing infection rates are 0.8
20 percent for those who received conductive
21 fabric warming versus about 3 percent --

22 A. Correct.

23 Q. -- for those who received forced-air warming,
24 correct?

25 A. Yes.

1 NACHTSHEIM

2 Q. Just so we are on the same page, the
3 infection rates discussed in the McGovern
4 article pertain only to periprosthetic joint
5 infections, correct, hip or knee?

6 A. Hip -- hip or knee, yes.

7 Q. Table 3 reflects that?

8 A. I believe it does. Hold on.
9 (Reviews document.) Oh, yeah. Yes, it does.

10 Q. So the McGovern study did not analyze or
11 collect data for a broader category of wound
12 infections more generally?

13 A. No.

14 Q. So it did not account for things such as
15 hematoma?

16 A. Correct.

17 Q. It did not account for superficial
18 infections?

19 A. Correct.

20 Q. The study does account for some patient
21 specific demographics, correct?

22 A. I just couldn't hear the last part.

23 MS. GARCIA: Objection --

24 BY MR. SACCHET:

25 Q. Some patient specific demographics?

1 NACHTSHEIM

2 A. Yes, it does.

3 MS. GARCIA: Object to the form of
4 the question.

5 BY MR. SACCHET:

6 Q. Some of those factors include age, correct?

7 A. Correct.

8 Q. Number of procedures, correct?

9 MS. GARCIA: I object to the form
10 of both of those questions.

11 BY MR. SACCHET:

12 Q. If I can direct your attention to table 1 --

13 A. Yeah, direct me.

14 Q. -- on page 1541.

15 A. Oh, table -- table 1, page 1541.

16 Q. Correct, number of -- yes.

17 MS. GARCIA: Could you clarify
18 what you mean by, "Account for"?

19 MR. SACCHET: They had collected
20 data from and analyzed whether those
21 demographics had statistical significance.

22 THE WITNESS: Yes.

23 BY MR. SACCHET:

24 Q. Another is diabetes, correct?

25 A. Correct.

1 NACHTSHEIM

2 Q. And the last is the duration of preoperative
3 hospital stay, correct?

4 A. Correct.

5 Q. And as to all four of those patient-specific
6 demographics, none of them were determined to
7 be statistically significant in terms of
8 affecting the infection rates that were
9 analyzed in the paper, correct?

10 MS. GARCIA: Object to the form of
11 that question, it misstates the paper.

12 THE WITNESS: What these showed
13 was that there were no statistically
14 significant differences in the groups for
15 age -- for the percentages of -- the
16 percentages of the procedures, the
17 percentages of diabetes and so forth.

18 BY MR. SACCHET:

19 Q. And if we turn back to table 2 on page 1542.

20 A. (Complies.)

21 Q. Although those factors were not significant
22 between each factors, for example, age is not
23 significantly different -- did not
24 significantly affect infection rates between
25 those age populations, there was a

1 NACHTSHEIM

2 significant difference between the device
3 that was used, correct?

4 MS. GARCIA: Object to the form of
5 the question.

6 THE WITNESS: Correct.

7 BY MR. SACCHET:

8 Q. Based on your review and expertise in the
9 field of statistics, do you continue to stand
10 by the calculations that were made in this
11 study?

12 A. I do.

13 Q. Do you have any reason to doubt
14 Mr. Albrecht's calculations or your review of
15 the calculations that are presented in this
16 paper?

17 A. I do not.

18 Q. This paper and this section of the paper was
19 also part of the peer review process,
20 correct?

21 A. Correct.

22 Q. So at least one third party looked at the
23 data presented and determined that it was
24 suitable for publication in this journal,
25 correct?

1 NACHTSHEIM

2 A. Correct.

3 Q. Although the data was observational in
4 nature, you still deemed the data worthy of
5 publication, correct?

6 A. Yes.

7 Q. And although observational data does not
8 necessarily equate to data that would be
9 derived from a randomized controlled trial,
10 observational data still has scientific
11 weight, correct?

12 A. Yes.

13 Q. Some statisticians view observational data as
14 level 3 or level 2 evidence compared to
15 level 1 evidence being generated from a
16 controlled trial, correct?

17 MS. GARCIA: Object to the form of
18 the question.

19 THE WITNESS: I had never heard
20 the terminology level 1, level 2, level 3,
21 but -- but certainly many of my colleagues
22 would -- would consider observational data as
23 secondary to experimental data in terms of --
24 in terms of showing an effect.

25 BY MR. SACCHET:

1 NACHTSHEIM

2 Q. And from observational studies you can derive
3 an association, correct?

4 A. Yes.

5 Q. And there are many circumstances in which
6 randomized controlled trials are not possible
7 to conduct, correct?

8 A. Correct.

9 Q. One of those circumstances, as you previously
10 mentioned, was with tobacco, correct?

11 A. Correct.

12 Q. And we're all well familiar with the fact
13 that tobacco causes cancer, correct?

14 A. Correct.

15 Q. But at the time there were only
16 observation --

17 MS. GARCIA: Object to the form of
18 the question.

19 BY MR. SACCHET:

20 Q. -- there were only observational studies in
21 order to demonstrate that association,
22 correct?

23 A. Correct.

24 Q. Why were -- why were randomized controlled
25 trials not possible with respect to the

1 NACHTSHEIM

2 tobacco subject matter?

3 MS. GARCIA: Object to the form of
4 the question.

5 THE WITNESS: Because of the
6 ethics involved, because you would need to
7 take a group of people and randomly split
8 them into two groups and tell one that you're
9 going to have to smoke two packs a day for
10 the rest of your life and the other group say
11 you can't smoke, so you can't do that.

12 BY MR. SACCHET:

13 Q. Are you aware of any reasons why it would be
14 difficult to conduct a randomized controlled
15 trial evaluating infection rates among
16 patients who receive different types of
17 patient-warming therapy?

18 A. I'm not -- I'm not aware of any technical
19 reasons why it couldn't be done, so I -- I
20 don't see why it couldn't be done.

21 Q. Have you --

22 A. Yeah --

23 Q. -- heard from anyone that it would be nearly
24 impossible to conduct such a randomized
25 controlled trial?

1 NACHTSHEIM

2 A. No. The only thing I heard was what -- is
3 what Mark mentioned in an e-mail saying he
4 thought it might cost \$2 million, but I don't
5 know where that number came from.

6 Q. Uh-huh. If we could turn back to Exhibit 19,
7 which is the e-mail that you were just
8 discussing.

9 A. Okay.

10 Q. Do you recall the specifics of the statement
11 that was made in the last quote that you
12 mention in this e-mail?

13 MS. GARCIA: I'm sorry, if you
14 could pause, because I don't think my Exhibit
15 19 is matching up with your conversation. Do
16 you have Exhibit 19 matching up with these
17 questions? Oh --

18 THE WITNESS: Oh, yes.

19 MS. GARCIA: -- I'm sorry, are you
20 on the last sentence of the first paragraph
21 of Mark's January 4, 2011, e-mail, is that
22 what you're referring to?

23 MR. SACCHET: Yeah.

24 MS. GARCIA: Okay. Thank you. It
25 took me a minute to get there.

1 NACHTSHEIM

2 MR. SACCHET: Yeah, no worries.

3 BY MR. SACCHET:

4 Q. Do you recall the specifics of the article
5 that you and Mr. Albrecht were discussing?

6 MS. GARCIA: Object to the form of
7 the question.

8 THE WITNESS: You know what, I
9 don't remember that we were discussing a
10 particular article.

11 BY MR. SACCHET:

12 Q. Do you see on the first page where
13 Mr. Albrecht sends you a hyperlink with a
14 New York Times --

15 A. Yes.

16 Q. -- website?

17 A. Yes. Oh, yes, and -- right. That was a
18 New York Times article. But I think we were
19 discussing what came from that article was
20 generally the discussion about could -- could
21 the use of the Bair Hugger and forced-air
22 warming lead to higher infection rates --

23 Q. And --

24 A. -- is there a causal link kind of thing.

25 Q. -- when you were previously asked a question

1 NACHTSHEIM

2 about this article, you mentioned that you
3 thought that the data referred to in the
4 article pertained to the McGovern article,
5 correct?

6 MS. GARCIA: Object to the form of
7 the question.

8 THE WITNESS: I don't remember.
9 And you're talking about the observational
10 data?

11 MR. SACCHET: Yeah.

12 THE WITNESS: I'm afraid I just
13 don't remember right now. Did I --

14 MR. SACCHET: That's okay, we'll
15 just --

16 MS. GARCIA: That's not what I
17 intend with my question.

18 MR. SACCHET: I just want to
19 clarify it for the record, because I think
20 the record reads differently.

21 BY MR. SACCHET:

22 Q. Does this article in the bottom left-hand
23 portion of the page reflect the web address
24 noted on the first page of Exhibit 19?

25 MS. GARCIA: Can we mark this?

1 NACHTSHEIM

2 MR. SACCHET: Sure.

3 THE WITNESS: Yes.

4 (Whereupon, Exhibit 26 was
5 marked for identification.)

6 MR. SACCHET: I believe it was
7 marked, was it?

8 THE WITNESS: Yeah, this is
9 Exhibit 26.

10 BY MR. SACCHET:

11 Q. So does the website address at the bottom
12 left-hand corner of Exhibit 26 --

13 A. Oh, does it match, I see what you're saying.

14 Q. -- match the --

15 A. Yes, it does. It does.

16 Q. If you could take a moment to just scan the
17 three odd pages of the article.

18 A. (Reviews document.)

19 MS. GARCIA: Is there a question?

20 MR. SACCHET: There's not one
21 pending.

22 MS. GARCIA: Okay. Thank you.

23 THE WITNESS: (Reviews document.)
24 Okay.

25 BY MR. SACCHET:

1 NACHTSHEIM

2 Q. Just a few quick questions about the article.

3 Did you find any reference to the
4 McGovern study or the McGovern data in the
5 article?

6 A. I did not.

7 Q. This study was -- or this article from the
8 New York Times was in fact published
9 approximately 11 months before the McGovern
10 article was published, wasn't it?

11 A. Yes, it was.

12 Q. The only data mentioned in the article are
13 those presented to the ECRI Institute that
14 you can find at the top of the last full text
15 page, correct?

16 A. Yes.

17 Q. And at the bottom of the article is
18 presumably what you and Mr. Albrecht were
19 referring to in your correspondence marked in
20 Exhibit 19 in which you say something to the
21 effect of, "His statement is hard to argue
22 with," correct?

23 MS. GARCIA: Object to the form of
24 the question.

25 THE WITNESS: I just wanted to

1 NACHTSHEIM

2 review where that shows up. Is that --

3 MR. SACCHET: That's --

4 THE WITNESS: That's what --

5 MR. SACCHET: Exhibit --

6 THE WITNESS: Oh, yes, "Hard to
7 disagree with the last quote" --

8 MR. SACCHET: The last quote.

9 THE WITNESS: -- "where the guy
10 said the data are compelling, but they don't
11 prove a link to infections in practice and a
12 clinical trial would be needed to do that?

13 MR. SACCHET: Yup.

14 BY MR. SACCHET:

15 Q. And the last quote also says that, "Proving
16 such a link might be impossible, because it
17 would require mounting a huge clinical
18 study," correct?

19 A. Correct.

20 Q. In the absence of a clinical study, is the
21 next best evidence observational data?

22 MS. GARCIA: Object to the form of
23 the question.

24 THE WITNESS: Yes. In the absence
25 of a -- of an experimental or a clinical

1 NACHTSHEIM

2 study, it's the -- the only evidence you
3 would have would be observational data.

4 BY MR. SACCHET:

5 Q. And you agreed with the statement made by
6 Dr. Jeffrey Gumprecht that it would be
7 impossible to mount a huge clinical study,
8 correct?

9 MS. GARCIA: Object to the form of
10 the question.

11 THE WITNESS: I -- I really -- I
12 really don't know for sure that it would be
13 impossible. I don't know what -- first of
14 all, I think it's possible. I don't know
15 what it would cost. I don't know -- I'd have
16 to think through how that kind of study would
17 be designed and -- and -- and the logistical
18 problems that might present themselves. I
19 don't see any impossibility.

20 MR. SACCHET: Okay.

21 BY MR. SACCHET:

22 Q. Assuming a randomized control trial could not
23 be conducted, observational data would be the
24 next best alternative?

25 MS. GARCIA: Object to the form of

1 NACHTSHEIM

2 the question.

3 THE WITNESS: That would be the
4 next best alternative.

5 BY MR. SACCHET:

6 Q. Why is that?

7 A. Here what we're doing with the -- with the
8 randomized -- with a clinical trial is that
9 we're going to actually put both -- both
10 types of blankets in practice and we can look
11 at -- look directly at infection rates that
12 result from the two different conditions, and
13 that's the -- that's the clinical study. If
14 you're looking at -- if you want to know
15 about infections, I think you're limited to
16 looking at observational studies such as --
17 such as the one that we report on.

18 We did -- we did experimental
19 studies on bubbles, but we can't do
20 experimental studies on infections without --
21 without resorting to a clinical trial of some
22 kind.

23 So I think that, yeah, I think you
24 probably -- if you want to look at
25 infections, I think you're -- I think you're

1 NACHTSHEIM

2 probably limited to observational data.

3 Q. Isn't it true that a well-designed
4 observational study can render results
5 extremely similar to a properly conducted
6 randomized trial --

7 MS. GARCIA: Object --

8 BY MR. SACCHET:

9 Q. -- on the same subject matter?

10 MS. GARCIA: Object to the form of
11 the question.

12 THE WITNESS: I think that can
13 happen, but I don't believe that the level of
14 proof reaches the same -- I don't think that
15 the proof reaches the same level of rigor.
16 There's just always that chance in
17 observational studies that -- I mean, I think
18 there's a greater chance that something -- a
19 confounding factor might be present,
20 something you just hadn't thought of.

21 BY MR. SACCHET:

22 Q. But it is possible that if statistical
23 significance is found based on observational
24 data, that that significance may be
25 replicated in a randomized control trial?

1 NACHTSHEIM

2 A. Yes.

3 Q. So the observational data that is presented
4 in the McGovern study is certainly valuable,
5 is it not?

6 MS. GARCIA: Object to the form of
7 the question.

8 THE WITNESS: I think it's
9 valuable.

10 BY MR. SACCHET:

11 Q. That's why you published the observational
12 data, correct?

13 A. Yes.

14 Q. You were previously asked about potentially
15 confounding factors with respect to the
16 observational data that was presented in the
17 McGovern study, correct?

18 A. Correct.

19 Q. And some of those potentially confounding
20 factors dealt with infection control
21 measures, correct?

22 A. Correct.

23 Q. If we could turn to page 1540 of Exhibit 4,
24 the McGovern study.

25 A. (Complies.)

1 NACHTSHEIM

2 Q. I want to make sure that we are on the same
3 page with respect to the change that occurred
4 as to the antibiotic regime. Would you agree
5 that an antibiotic called Gentamycin was
6 applied during the forced-air warming period
7 from July 1st, 2008, to the end of February
8 2009? It's about halfway down the paragraph.

9 A. I see it. From July 2008 to February 2009 a
10 single dose of Gentamicin 4.5 was given at --
11 at induction.

12 Q. Whereas, a combination of Gentamycin and
13 Teicoplanin -- and I'd be surprised if any of
14 us know how to pronounce it, but that's how
15 I'm going to say it -- was applied during the
16 end of the forced-air warming period and
17 throughout the entire conductive fabric
18 warming period, which would namely be
19 March 1st, 2009, until January 2011, correct?

20 MS. GARCIA: Can you please point
21 to where you're reading from?

22 MR. SACCHET: So I am interpreting
23 what's said in this paragraph and based on
24 what's presented in Figure 7 so --

25 MS. GARCIA: Okay. Then I'll

1 NACHTSHEIM

2 object to the form of the question.

3 THE WITNESS: I -- I read this --

4 MR. SACCHET: I can walk through
5 it slower.

6 THE WITNESS: Well, I read this to
7 say that in March 2009 there was a change to
8 the combination of the two drugs you've
9 pronounced, and I don't believe there were
10 any changes until the end of the study.

11 MR. SACCHET: Okay.

12 BY MR. SACCHET:

13 Q. So -- so we're clear, there was a period in
14 which Gentamycin was applied to some
15 forced-air warming patients, and then the
16 antibiotic changed to a combination of
17 Gentamycin and Teicoplanin that applied to
18 some forced-air warming patients and all of
19 the conductive fabric warming patients,
20 correct?

21 A. Correct.

22 Q. Assuming the change in antibiotic did not
23 affect infection rates between warming
24 devices, would you still consider the
25 antibiotic a confounding variable?

1 NACHTSHEIM

2 MS. GARCIA: Object to the form of
3 the question.

4 THE WITNESS: I'm going to assume
5 that it has -- the change had no effect?

6 BY MR. SACCHET:

7 Q. Yeah, assume that the antibiotic had no
8 effect on the infection rate. Would it still
9 be a confounding variable?

10 MS. GARCIA: Object to the form of
11 the question.

12 THE WITNESS: I don't think it
13 would be -- I don't think it would be
14 considered a confounding variable. I'm
15 trying to think of how else it might have an
16 impact, if it's not having an effect. I
17 guess it -- no, I don't think it would be,
18 yeah.

19 BY MR. SACCHET:

20 Q. One way that we could control for the -- let
21 me strike that.

22 In order to determine whether the
23 antibiotic had an effect on infection rates,
24 we could control for the warming device --

25 A. Yes.

1 NACHTSHEIM

2 Q. -- and evaluate whether infection rates
3 between the changed antibiotic stayed the
4 same or went up or down --

5 A. Correct.

6 Q. -- with that control device, correct?

7 A. (Nods head.)

8 MS. GARCIA: I'm going to object
9 to the form of the question.

10 BY MR. SACCHET:

11 Q. Did you understand it?

12 A. Yes.

13 Q. If infection rates between the two groups
14 were similar, that would tend to show that
15 the antibiotic was not a confounding factor?

16 A. Correct.

17 MS. GARCIA: Object to the form of
18 the question.

19 BY MR. SACCHET:

20 Q. Assume that Mr. Albrecht, who you previously
21 mentioned was an expert in statistics and you
22 had full confidence in his ability to analyze
23 data presented in this article, informed you
24 that he found a 2.8 percent infection rate in
25 those who received Gentamycin, a single drug,

1 NACHTSHEIM

2 but 3.1 percent of patients who received the
3 combination of antibiotics, but also
4 forced-air warming patients, with a nearly
5 identical infection rate, would you determine
6 that the antibiotic was a confounding factor?

7 MS. GARCIA: Object to the form of
8 the question.

9 THE WITNESS: That would be strong
10 evidence that it was not a confounding
11 factor.

12 MR. SACCHET: Let's mark this.

13 (Whereupon, Exhibit 27 was
14 marked for identification.)

15 BY MR. SACCHET:

16 Q. So just to be clear, if we look at this table
17 that's presented here, we can see in the
18 first line it presents antibiotic protocol 1
19 versus 2 for FAW, does it not?

20 A. It does.

21 Q. Assume that protocol 1 is the singular
22 antibiotic, i.e. Gentamycin, and that
23 protocol 2 is the combination of Gentamycin
24 and Teicoplanin.

25 A. Uh-huh. Yes.

1 NACHTSHEIM

2 Q. In this particular analysis, forced-air
3 warming is held constant, correct?

4 A. Correct.

5 Q. And for forced air, protocol 1, the percent
6 of patients developing infection was 2.8?

7 A. Correct.

8 Q. And for forced air, protocol 2, involving
9 patients who received both Gentamycin and
10 Teicoplanin, the infection rate was 3.1,
11 correct?

12 A. Correct.

13 Q. And the p-value was 0.839, correct?

14 A. That's what's reported here.

15 Q. That's what's reported here. We could
16 conclude, based on this data set of these
17 numbers, that when the patient-warming device
18 is held constant, that the change in
19 antibiotic had no effect on infection rates,
20 correct?

21 MS. GARCIA: Object to the form of
22 the question.

23 THE WITNESS: Assuming there's
24 sufficient power in those sample sizes,
25 although they look fairly large to me, yes.

1 NACHTSHEIM

2 BY MR. SACCHET:

3 Q. The patient population for forced-air
4 protocol 1 was 389 patients, correct?

5 A. Correct.

6 Q. And the patient population for those
7 receiving the combination was 678, correct?

8 A. Correct.

9 Q. Those are fairly large patient populations,
10 correct?

11 A. Correct.

12 MS. GARCIA: Object to the form of
13 the question.

14 BY MR. SACCHET:

15 Q. Another way to determine whether the
16 antibiotic was a confounding variable would
17 be to control the antibiotic, but evaluate
18 different infection rates between different
19 forced-air -- or different warming devices,
20 correct?

21 A. Yes.

22 MS. GARCIA: Object to the form of
23 that question also.

24 BY MR. SACCHET:

25 Q. And if the infection rates were still higher

1 NACHTSHEIM

2 among those who received forced-air warming
3 compared to those who received conductive
4 fabric warming, that would tend to show the
5 antibiotic did not substantially affect
6 infection rates, correct?

7 A. Correct.

8 MS. GARCIA: Object to the form of
9 the question.

10 BY MR. SACCHET:

11 Q. And if that's true, the change in antibiotic
12 would also not be a confounding factor,
13 correct?

14 A. Correct.

15 MS. GARCIA: Object to the form of
16 the question.

17 BY MR. SACCHET:

18 Q. If I could --

19 MR. SACCHET: Could I ask your
20 basis for the objection?

21 MS. GARCIA: I'm sorry?

22 MR. SACCHET: Could I ask your
23 basis for the objection on form?

24 MS. GARCIA: Yes. You keep using
25 the word, "determine," and you keep using the

1 NACHTSHEIM

2 word, "show," and you keep using the word,
3 "establish," and I'm objecting to the form of
4 the question based on those terms.

5 MR. SACCHET: That's not going to
6 pass muster in the court.

7 BY MR. SACCHET:

8 Q. As to the hypothetical I just presented, if
9 you could turn your attention to the second
10 line of the table.

11 MS. GARCIA: I'm sorry, to just be
12 complete with my form objection, it's also an
13 incomplete hypothetical.

14 MR. SACCHET: Fair enough.

15 BY MR. SACCHET:

16 Q. Antibiotic protocol 2 involved a combination
17 have Gentamycin and Teicoplanin, correct?

18 MS. GARCIA: Object to
19 foundation --

20 BY MR. SACCHET:

21 Q. -- for the sake of --

22 A. Yes.

23 MS. GARCIA: Excuse me. Object to
24 foundation for that.

25 BY MR. SACCHET:

1 NACHTSHEIM

2 Q. And the data here shows that 3.1 percent of
3 patients who received forced-air warming in
4 the combination antibiotic developed joint
5 infections, correct?

6 A. Correct.

7 Q. Whereas, .9 percent of patients who received
8 conductive fabric warming and the combination
9 of antibiotics developed joint infections,
10 correct?

11 A. Correct.

12 Q. By holding the antibiotic constant and
13 discontinuing the use of forced-air warming,
14 that resulted in a 71 percent decrease in
15 joint infections, did it not?

16 MS. GARCIA: Object to the form of
17 the question.

18 THE WITNESS: Yes, it did.

19 BY MR. SACCHET:

20 Q. That essentially matches the 73 percent
21 decrease in infections that was noted in the
22 McGovern article itself, does it not?

23 A. Correct.

24 MS. GARCIA: Object to the form of
25 the question.

1 NACHTSHEIM

2 BY MR. SACCHET:

3 Q. And based on the p-value of .0008, which is
4 far less than .05, you would determine that
5 difference to be statistically significant,
6 would you not?

7 A. I would.

8 Q. So whether we control for the device or
9 control for the antibiotic, based on this
10 data set in Exhibit 27, would you determine
11 that the antibiotic was not a confounding
12 factor?

13 MS. GARCIA: Object to the form of
14 the question, it's a lack of foundation, it's
15 an incomplete hypothetical.

16 THE WITNESS: This data certainly
17 supports that hypothesis.

18 BY MR. SACCHET:

19 Q. And if it were not a confounding factor,
20 would there be any reason to deselect
21 patients from the population of 1,437
22 accounted for in the McGovern study in order
23 to exclude those who received a single
24 antibiotic?

25 A. No.

1 NACHTSHEIM

2 MS. GARCIA: Object to the form of
3 the question.

4 BY MR. SACCHET:

5 Q. And if we were to do that and reduce the
6 population, let's say, from the 1,473, or 37,
7 I've forgotten which number it is, down to a
8 number of let's say 500 patients, there could
9 be concern about the powering of that
10 population?

11 A. There could. There could be.

12 Q. Another confounding factor that was discussed
13 this afternoon was a change in the
14 thromboprophylaxis protocol, correct?

15 A. Yes. Can -- can you just remind me where
16 that --

17 Q. Yeah, if we could turn to page 1540.

18 A. (Complies.)

19 Q. If you look at the bottom of the first full
20 paragraph in the left-hand column, it states
21 the thromboprophylaxis regimen from
22 July 2008 to the end of July 2009 was
23 Tinzaparin.

24 A. Uh-huh.

25 Q. Then it says from August 2009 to February

1 NACHTSHEIM

2 2010, Rivaroxaban, which I'll represent is
3 otherwise known as Xarelto, was provided from
4 day one, but in February 2010 to the end of
5 this study, patients were reverted to
6 Tinzaparin, correct?

7 A. Yes.

8 Q. Assuming the change in the prophylaxis did
9 not affect infection rates during the time of
10 this study, i.e., Exhibit 4, would you still
11 consider it a confounding variable?

12 A. No.

13 MS. GARCIA: Object to the form of
14 the question.

15 (Whereupon, Exhibit 28 was
16 marked for identification.)

17 MS. GARCIA: What number are we
18 on?

19 MR. SACCHET: Twenty-eight, I
20 believe.

21 THE COURT REPORTER: Correct.

22 MS. GARCIA: Thank you.

23 BY MR. SACCHET:

24 Q. Have you seen this document before,
25 Professor?

1 NACHTSHEIM

2 A. No, I have not.

3 Q. Was this document produced with the set of
4 documents that you provided to 3M in response
5 to the subpoena?

6 A. No.

7 Q. Does the bottom right-hand label of this
8 document bear a Bates number of Nachtsheim --

9 A. It does.

10 Q. -- space 0000451?

11 A. It must have been attached to one of my
12 e-mails. I -- I -- I don't remember seeing
13 the document.

14 Q. Since you don't remember receiving or reading
15 the document, let's go through it.

16 A. Okay.

17 Q. If you'd turn to the second page of text that
18 bears the heading, "Introduction"; do you see
19 that?

20 A. I do.

21 Q. Do you see the last paragraph at the bottom
22 of that page?

23 A. "This multicenter study"?

24 Q. Correct. I'll read it out loud and you just
25 confirm that we're on the same page. "This

1 NACHTSHEIM

2 multicenter study based on prospectively
3 collected national data aims to evaluate the
4 surgically relevant complications of using
5 either Rivaroxaban, or LMWH," which I'll
6 represent means low molecular weight
7 heparins, "as thromboprophylaxis, including
8 wound complications, readmission and return
9 to theater for deep infection, in addition to
10 the incidents of major bleeds and EVT,"
11 correct?

12 A. Correct.

13 Q. Based on that statement, do you agree that at
14 least two or three outcomes were measured,
15 one being wound complications, another being
16 return to theater for deep infection, and
17 another being major bleeds?

18 A. I agree.

19 MS. GARCIA: I object to lack of
20 foundation.

21 BY MR. SACCHET:

22 Q. If you could turn to the next page under,
23 "Methods," in the third paragraph it states,
24 "The primary outcome measure was wound
25 complications," parens, "Including hematoma,

1 NACHTSHEIM

2 superficial wound infection and deep
3 infection requiring return to theater, RTT,
4 within 30 days of procedure"; do you see
5 that?

6 A. I do.

7 Q. And you see the designation that RTT involves
8 a deep infection requiring a return to
9 theater, correct?

10 A. Correct.

11 Q. Which is one of the independent variables
12 that was mentioned in the prior paragraph
13 that we read, correct?

14 MS. GARCIA: Object to the form of
15 the question.

16 THE WITNESS: Correct. I think
17 dependent variables.

18 MR. SACCHET: Okay. Noted.

19 BY MR. SACCHET:

20 Q. If we can now turn to the next page under,
21 "Results," do you see that heading?

22 A. Yes, 456.

23 Q. It says, "During the study period, 2,762
24 patients received Rivaroxaban, and 10,361
25 received LMWH. Patient demographics are

1 NACHTSHEIM

2 shown in table 1. There were significantly
3 fewer wound complications in the LMWH group,"
4 parens, "2.81 percent versus 2.85 percent, OR
5 equals .72, 95 percent confidence intervals
6 between 0.58 to 0.90 with a p-value of .005.
7 However, rates of RTT for infected wound
8 washout were not significantly different."
9 Do you see that?

10 A. I do.

11 Q. Assuming the truth of this study in what we
12 just read, would you agree that Rivaroxaban,
13 otherwise known as Xarelto, increased wound
14 complications compared to low weight
15 molecular heparins like Tinzaparin?

16 MS. GARCIA: Object to the form of
17 the question, to an incomplete hypothetical
18 and to a lack of foundation for this witness
19 to opine about the meaning of this article.

20 THE WITNESS: It says there were
21 significantly fewer wound complications in
22 the LMH -- LMWH group. Is that what you're
23 referring to?

24 BY MR. SACCHET:

25 Q. That's what I'm referring to. And the

1 NACHTSHEIM

2 p-value was a statistically significant
3 value, correct?

4 A. Yes, correct.

5 Q. So there were fewer wound complications as a
6 result of the use of a low weight molecular
7 heparin --

8 A. Correct.

9 Q. -- compared to Rivaroxaban, correct?

10 A. Yeah, correct.

11 MS. GARCIA: Object to the form of
12 the question.

13 BY MR. SACCHET:

14 Q. However, the study notes that rates for RTT,
15 which we established to be a return to
16 theater for --

17 A. Uh-huh.

18 Q. -- infections, were not significantly
19 different; do you see that?

20 A. Correct. Yes, I do.

21 Q. Assuming the truth -- well, let me back up.

22 Would you also agree that the
23 McGovern study, Exhibit --

24 MS. GARCIA: Four.

25 BY MR. SACCHET:

1 NACHTSHEIM

2 Q. -- 4, evaluated joint infections?

3 A. Yes.

4 Q. It did not evaluate wound complications, did
5 it?

6 A. Correct, it did not.

7 Q. Assuming the truth of this study, would you
8 ultimately agree that the change in protocol
9 from Tinzaparin, which is an LMWH, to
10 Xarelto, otherwise known as Rivaroxaban, and
11 then back to Tinzaparin, did not
12 significantly affect the infection rate?

13 MS. GARCIA: Object to the form of
14 the question, to lack of foundation, and it's
15 an incomplete hypothetical.

16 THE WITNESS: Assuming the study
17 was carefully done and generalizable, yes.

18 BY MR. SACCHET:

19 Q. And assuming the study was well done and
20 generalizable, would you agree that the
21 change in thromboprophylaxis noted in the
22 McGovern study, Exhibit 4, did not confound
23 the infection rates?

24 MS. GARCIA: Object to the form of
25 the question.

1 NACHTSHEIM

2 THE WITNESS: Assuming -- yes.

3 BY MR. SACCHET:

4 Q. And would you also conclude that, assuming
5 the truth of this study, it would be improper
6 to deselect all of the patients who received
7 Xarelto, otherwise known as Rivaroxaban, from
8 the patient population if the
9 thromboprophylaxis was not a confounding
10 variable?

11 MS. GARCIA: Object to the form of
12 the question.

13 THE WITNESS: It doesn't seem
14 justified in -- on the basis of these
15 results.

16 BY MR. SACCHET:

17 Q. And, in fact, when the coauthors of the
18 McGovern study were in the process of
19 publication, are you aware that at numerous
20 times they sought to collect additional data
21 in support of the study?

22 A. I was not aware of that. I knew that -- I
23 knew that they sought to run this study out
24 in time.

25 Q. Are you aware that when Mr. Albrecht and

1 NACHTSHEIM

2 Dr. Reed collected additional data that went
3 beyond January 2011 in the conductive fabric
4 warming population, that the data still
5 showed a significant decrease in infections
6 when conductive fabric warming was used?

7 A. I'm aware of that.

8 Q. Assuming that --

9 MS. GARCIA: Can we take a break
10 shortly?

11 MR. SACCHET: Yeah, give me two
12 minutes.

13 BY MR. SACCHET:

14 Q. Assuming that neither the antibiotic nor the
15 thromboprophylaxis protocol required control
16 because they were not confounding factors as
17 we discussed, you would be confident in the
18 results of the observational study presented
19 in the McGovern data?

20 MS. GARCIA: Object to the form of
21 the question.

22 THE WITNESS: I'm confident that
23 those weren't confounding factors, that those
24 studies are well done. It doesn't rule out
25 the potential for other confounding factors.

1 NACHTSHEIM

2 MR. SACCHET: Fair enough.

3 BY MR. SACCHET:

4 Q. And you continue to stand by the results of
5 the observational studies --

6 A. Yes.

7 Q. -- in the McGovern publication?

8 A. I do.

9 MR. SACCHET: Let's take a break.

10 THE VIDEOGRAPHER: We're going off
11 the record at 5:07 p.m.

12 (Whereupon, a brief recess
13 was taken.)

14 THE VIDEOGRAPHER: This is video
15 number 6 in the deposition of Christopher
16 Nachtsheim. Today is November 29th, 2016.
17 We're going back on the record at 5:18 p.m.

18 BY MR. SACCHET:

19 Q. Professor Nachtsheim, if we could turn to
20 Exhibit 5, which is the Belani study.

21 A. I have it.

22 Q. Great. And as to this study, your role was
23 to exclusively review the statistical portion
24 of this study, correct?

25 A. Correct.

1 NACHTSHEIM

2 Q. You had no involvement in the setup of the
3 experiment?

4 A. I did not.

5 Q. You had no role in the execution of the
6 physical experiment?

7 A. I did not.

8 Q. You had seen, whether by video or in person,
9 disruption of laminar flow caused by the
10 Bair Hugger before, correct?

11 A. I had, yes.

12 MS. GARCIA: I'm sorry, can I hear
13 that question again? I was thinking and I
14 did not hear the question.

15 MR. SACCHET: Can you -- do you
16 mind repeating it.

17 (Whereupon, the last question
18 was read by the court reporter.)

19 MS. GARCIA: Object to the form of
20 the question, asked and answered.

21 BY MR. SACCHET:

22 Q. So you were familiar with the possibility,
23 based on your personal experience, that the
24 Bair Hugger could disrupt laminar airflow,
25 correct?

1 NACHTSHEIM

2 MS. GARCIA: Object to the form of
3 the question, misstates the record and lack
4 of foundation.

5 THE WITNESS: Correct.

6 BY MR. SACCHET:

7 Q. If we could turn to the third page of the
8 study.

9 A. (Complies.) 408?

10 Q. Yes. Do you see the header entitled,
11 "Statistical Analysis"?

12 A. I do.

13 Q. And it reads, "A Poisson regression model for
14 overdispersed data was fit having the sum of
15 bubble counts for each experimental run,"
16 paren, "ten pictures," end parens, "as the
17 response, and the factors identified in the
18 experimental design as predictors plus an
19 interaction term." Do you see that?

20 A. I do, yes.

21 Q. Did you determine that a Poisson regression
22 was the most appropriate statistical model to
23 employ because you were dealing with counts
24 data -- or data counts?

25 A. Yes.

1 NACHTSHEIM

2 MS. GARCIA: Object to the form of
3 the question, previously asked and answered.

4 BY MR. SACCHET:

5 Q. And that Poisson regression was a better
6 model to use than, let's say, an ANOVA model?

7 MS. GARCIA: Object to the form of
8 the question, previously asked and answered.

9 THE WITNESS: Yes.

10 BY MR. SACCHET:

11 Q. And if we could just turn our attention one
12 paragraph above that, it says, "For the
13 experimental design, a replicated and equals
14 to 2 by 3 full factorial design was used to
15 assess changes in bubble counts over the
16 surgical site," correct?

17 A. Correct.

18 Q. And what were the factors?

19 A. So the first factor is the anesthesia screen,
20 low grade/high grade, those are the two
21 levels, and then there were three
22 patient-warming devices, conductive fabric,
23 forced-air or no warming device, and that
24 would -- that was considered a control.

25 Q. Does Figure 3, directly above that paragraph,

1 NACHTSHEIM

2 reflect the full factorial design of this
3 study?

4 A. Yes, it does.

5 Q. The Y axis designates the drape height,
6 correct?

7 A. Yes, it -- it -- the Y axis designates the
8 drape height, right. But also going up the Y
9 axis, we're changing the three -- the three
10 levels of fabric, if you will.

11 Q. And the X axis designates the bubbles that
12 were counted for each run at a particular
13 drape height for a particular warming device,
14 correct?

15 A. Correct.

16 Q. Looking at the control for both drape heights
17 low and high, zero bubbles were counted,
18 correct?

19 A. Correct.

20 Q. And for conductive fabric, most of the runs
21 generated zero bubbles, correct?

22 A. Correct.

23 Q. It appears that there was only two instances
24 in which one bubble was generated, correct?

25 MS. GARCIA: Just -- I'm sorry, I

1 NACHTSHEIM

2 would just like to object to the form of
3 these questions for the use of the term
4 "generated."

5 THE WITNESS: Yes, that's -- that
6 is correct.

7 BY MR. SACCHET:

8 Q. In contrast to that data set, the bubble
9 counts for forced-air warming at both a low
10 and high drape count generally exceeded one
11 bubble, correct?

12 A. Correct.

13 Q. In fact, for one run there were nearly 7
14 bubbles counted, correct?

15 A. Correct.

16 Q. And for the majority of runs, at least two to
17 four bubbles were counted, correct?

18 A. At least, yes, correct.

19 Q. Based on the differences in bubble counts
20 between the use of a forced-air warming
21 device compared to a conductive fabric
22 warming device, the study concluded that
23 there was a statistically significant
24 difference, correct?

25 A. Correct.

1 NACHTSHEIM

2 Q. And that statistically significant difference
3 held a p-value of .001 for patient-warming
4 device, correct, as reflected in table 1?

5 A. Actually, less than .001.

6 Q. And such a low p-value would suggest that
7 there would be less than a 1 percent chance
8 of finding a false positive, otherwise known
9 as a difference that actually, in fact, does
10 not show a difference, correct?

11 A. Less than a .1 percent.

12 MS. GARCIA: Object to the form of
13 the question.

14 BY MR. SACCHET:

15 Q. The fact that only two trials were performed
16 with respect to each factor did not impact
17 the statistical significance of the result,
18 did it?

19 A. No. Let me answer -- let me be more careful
20 in my answer. We had two replicates of the
21 experiment, so each -- each experimental
22 condition was run twice, and yet the results
23 led to highly significant effect due to the
24 patient-warming device. So even with just
25 a -- just two replicates at each, we were

1 NACHTSHEIM

2 able to find highly statistically significant
3 results.

4 Q. So in other words, even though there were
5 only two trials, the study was still
6 adequately powered?

7 A. Yes.

8 Q. Because you could reject the null hypothesis
9 of equivalent bubble counts --

10 A. Correct.

11 Q. -- between the two devices?

12 A. Correct.

13 Q. If we could look at the, "Results," section
14 on the same page, it states, "In reviewing
15 the raw bubble count data," parens, "Figure
16 3," end parens, "It is apparent that there is
17 a large increase in the number of bubbles
18 reaching the surgical site when forced-air
19 warming is in use versus either conductive
20 fabric warming or control conditions.
21 Furthermore" --

22 MS. GARCIA: I'm sorry, I can't
23 find where you are.

24 MR. SACCHET: Okay. I'm at the
25 bottom left-hand corner of the same page --

1 NACHTSHEIM

2 MS. GARCIA: Thank you. I've got
3 it now.

4 MR. SACCHET: Okay. Do you want
5 me to read it again?

6 MS. GARCIA: You can continue.

7 MR. SACCHET: Okay.

8 BY MR. SACCHET:

9 Q. -- "or controlled conditions. Furthermore,
10 this increase seems to be independent of
11 drape height." Do you stand by --

12 A. Yes.

13 Q. -- the text of this paragraph?

14 A. Yes, I do.

15 Q. And the paragraph goes on to state on the
16 right-hand column, the carry-over paragraph,
17 "With the full additive model, the use of
18 forced-air warming was found to result in
19 a" --

20 A. Wait, excuse me -- oh, I see where you are
21 now. Okay. I'm sorry. Continue.

22 Q. -- "With the full additive model," parens,
23 "Figure 4," end parens, "The use of
24 forced-air warming was found to result in a
25 predicted mean sum of bubble counts equal to

1 NACHTSHEIM

2 132.5 when averaged across both anesthesia
3 drape heights. Such a count represents a
4 significant increase in the number of bubbles
5 reaching the surgical site versus both
6 conductive fabric warming, the p-value of
7 .003 and control conditions with the p-value
8 .008, which had predicted mean sum of bubble
9 counts equal to 0.48 and 0.01 respectively."

10 Do you agree with that statement?

11 A. I do.

12 Q. Is my understanding correct that the sum of
13 bubble counts for forced-air warming was 132
14 versus a sum of bubble counts for conductive
15 fabric warming of 0.48?

16 A. The -- the -- the predicted sum of bubble
17 counts was 132.5. And, I'm sorry, what was
18 the other one you --

19 Q. 0.48 corresponding to conductive fabric
20 warming.

21 A. Right. Yes.

22 Q. Assuming that bubbles were a proxy for
23 bacteria, would you stand by the conclusion
24 that there was a difference of nearly 132
25 bacterial particles with the use of

1 NACHTSHEIM

2 forced-air warming versus conductive fabric
3 warming?

4 MS. GARCIA: Object to the form of
5 the question, it's an incomplete
6 hypothetical, it misstates the paper and
7 there is a lack of foundation.

8 THE WITNESS: If bubbles could be
9 used as a proxy, then that's true.

10 BY MR. SACCHET:

11 Q. This paper, like the McGovern paper, was
12 submitted to a scientific journal, correct?

13 A. Correct.

14 Q. Unlike the McGovern study, it was submitted
15 to Anesthesia & Analgesia journal, correct?

16 A. Correct.

17 Q. Do you know whether an independent referee or
18 a third party reviewed the manuscript that
19 was submitted to the journal?

20 A. There -- there was a review.

21 Q. And the paper was ultimately published in
22 that journal, correct?

23 A. Correct.

24 Q. So a third party found that this data was
25 worthy of publication in a scientific

1 NACHTSHEIM

2 journal, correct?

3 A. Yes.

4 Q. Do you have any doubt about the statistical
5 work that Mr. Albrecht performed with respect
6 to this study?

7 A. I have no doubts about this, the statistical
8 work, I think it's fine.

9 Q. Would you consider the statistical model of
10 this study fairly straightforward?

11 A. Yes, very -- yes.

12 Q. And you were previously asked whether the
13 absence of particular variables in this
14 study, including lighting, instrument trays
15 and the like, might have an effect on the
16 bubble counts, correct?

17 A. Correct.

18 Q. It is possible that the presence of those
19 variables might increase bubbles or decrease
20 bubbles based on the use of a patient-warming
21 device, correct?

22 A. Correct.

23 Q. You have no knowledge as to whether the
24 inclusion of those variables would have
25 resulted in a reduced bubble count with

1 NACHTSHEIM

2 respect to the forced-air warming device, do
3 you?

4 A. No.

5 Q. The fact that you received consulting fees
6 from Augustine Biomedical or a successor
7 company did not influence your ability to
8 analyze this data, did it?

9 A. I hope not. I don't believe it did. We try
10 to be objective about everything we do. But,
11 no, it wouldn't have affected my analysis of
12 this data.

13 Q. The amounts that you received were normal
14 consulting fees, correct?

15 A. Correct.

16 MS. GARCIA: Object to the form of
17 the question.

18 BY MR. SACCHET:

19 Q. They were nothing out of the ordinary in
20 terms of other fees that you charged other
21 third parties to perform statistical
22 analysis, correct?

23 A. Correct.

24 Q. You were previously asked a series of
25 questions regarding an operating room in a

1 NACHTSHEIM

2 warehouse of sorts, correct?

3 A. Yes.

4 Q. And there were statements to the effect that
5 the results from the testing that had been
6 performed in that warehouse were,
7 quote/unquote, "goofy"; is that correct?

8 A. Correct.

9 Q. And you had mentioned that you were concerned
10 by some of the testing that had in fact
11 occurred in that warehouse, correct?

12 A. Correct.

13 Q. The experimental portion of the McGovern
14 study involving the simulated hip and lumbar
15 spine surgeries were not performed in that
16 warehouse, were they?

17 A. They were not performed in that warehouse.

18 Q. The experimental --

19 MS. GARCIA: Object to lack of
20 foundation on that.

21 BY MR. SACCHET:

22 Q. Where was the McGovern study performed?

23 A. I believe that was in the hospital. That was
24 the UK hospital, I believe.

25 Q. And the UK is not the same place as the

1 NACHTSHEIM

2 warehouse that you visited, is it?

3 A. Correct.

4 Q. With respect to the Belani study, do you know
5 where the experimental portion of the study
6 was performed?

7 A. It was performed in a University of Minnesota
8 Hospital.

9 MS. GARCIA: Objection; asked and
10 answered. And I would note for the record
11 that before we came on after this break you
12 told us that you were instructed by your
13 co-counsel, who you had called, to use up and
14 run out your time after I had asked for time
15 to redirect. And the video record will
16 reflect that there's been a marked decrease
17 in the pace of your questions. And at this
18 point you are simply going over things that
19 we have discussed extensively this morning
20 and all day long, and I do have a few
21 follow-up questions simply to clarify a
22 couple of things, and Professor Nachtsheim, I
23 would appreciate the opportunity to ask
24 those --

25 MR. SACCHET: I'm going to --

1 NACHTSHEIM

2 MS. GARCIA: -- just a few
3 questions.

4 MR. SACCHET: I'm going to object
5 to the recitation of what I represented
6 during the break --

7 MS. GARCIA: Did you say that?
8 Did you say that?

9 MR. SACCHET: -- because I
10 represented that I would be using the rest of
11 the time and that it was not going to be for
12 an improper purpose, but seven hours are
13 allotted for the deposition --

14 MS. GARCIA: You did say it was
15 your marching orders.

16 MR. SACCHET: -- and that seven
17 hours has been noted --

18 MS. GARCIA: You also said it was
19 your marching orders --

20 MR. SACCHET: -- and it's also my
21 choice.

22 MS. GARCIA: -- everyone in this
23 room heard it.

24 MR. SACCHET: And it's also my
25 choice.

1 NACHTSHEIM

2 MS. GARCIA: That's fair enough.

3 It is your choice. And your rate of
4 questioning has decreased markedly, and I'm
5 asking Professor Nachtsheim if he would be
6 willing to stay for a few moments so that I
7 can clarify a few things on the record.

8 MR. SACCHET: It's not the
9 deponent's choice.

10 MS. GARCIA: He can make a choice,
11 sure he can. He's allowed to make a choice,
12 absolutely.

13 MR. SACCHET: You want to subject
14 the deponent to the choice of whom he'd like
15 to receive questions from?

16 MS. GARCIA: I'm saying I have a
17 few clarifying questions based on questions
18 you asked him that are outside his area of
19 expertise, and I want to make sure the record
20 is clear about that.

21 MR. SACCHET: Well, I'd like to
22 finish my set of questions, and if there's
23 time for you to do that, I respect that. But
24 I'm not done with my line of questions. In
25 fact, I have a 30-page outline, which I've

1 NACHTSHEIM

2 addressed maybe 10 percent of it. So if
3 you're doubting the scope of my examination,
4 I can show you this and prove that my
5 examination would have lasted seven hours.

6 MS. GARCIA: Go right ahead.

7 MR. SACCHET: Do you want to see
8 it?

9 MS. GARCIA: No, I can see you
10 holding it.

11 MR. SACCHET: Okay. So --

12 MS. GARCIA: I would like you to
13 go ahead and ask your questions.

14 MR. SACCHET: I will.

15 BY MR. SACCHET:

16 Q. So going back to the question that I just
17 answered [sic], this study, the Belani study,
18 namely, was not conducted in the warehouse
19 that you previously mentioned --

20 A. Correct.

21 Q. -- this afternoon, correct?

22 A. Correct.

23 Q. Okay. And in the last paragraph, or the
24 second to last paragraph of the Belani study,
25 if you can turn your attention to the last

1 NACHTSHEIM

2 page.

3 A. Second to last paragraph?

4 Q. Actually, the third to last paragraph.

5 A. Okay.

6 Q. It states, "The most recent articles
7 published on the association between patient
8 warming excess heat and ventilation
9 disruption present contradictory conclusions.
10 Two studies conducted in the United Kingdom
11 that characterized both the thermal basis and
12 the airflow patterns supporting the physics
13 behind ventilation disruption in laminar
14 airflow ORs. In contrast, a published study
15 in the Netherlands found no evidence of
16 ventilation disruption due to forced air
17 excess heat when evaluated with the
18 DIN 1946:2008-12 standard. This discrepancy
19 in findings is likely related to two primary
20 differences in test methods"; do you see
21 that?

22 A. I do.

23 Q. Do you know what study is referred to by the
24 Netherlands study?

25 A. I'm actually not familiar with it. I've not

1 NACHTSHEIM

2 read it.

3 Q. If you turn to footnote 19, can you determine
4 what that study is?

5 A. Footnote 19 or reference 19? I'm --

6 Q. Yeah, I apologize, reference 19.

7 A. Sessler, Olmstead, Kuelpmann, "Forced-air
8 warming does not worsen air quality in
9 laminar flow operating rooms," is that --

10 Q. Have you ever read that study before?

11 A. I've not read that. I've not read that
12 study.

13 Q. Okay.

14 (Whereupon, Exhibit 29 was
15 marked for identification.)

16 MR. SACCHET: Well, I'll try to, I
17 guess, rush it up.

18 BY MR. SACCHET:

19 Q. If you could turn to the third page of this
20 study bearing the Bates number 3MBH0095630.

21 A. Okay. Where do you want me to focus?

22 Q. There are two figures there, one --

23 A. Oh, okay.

24 Q. -- presented at the top right-hand corner and
25 one directly beneath that.

1 NACHTSHEIM

2 A. Yup.

3 Q. Do you see that the X axis measures no air,
4 ambient air and warm air?

5 A. I do.

6 Q. And do you see that the Y axis measures
7 particle concentration?

8 A. I do.

9 Q. Do you see that the Y axis ranges in -- in
10 term from 1 to 10, to a hundred to a
11 thousand, to 10,000, a hundred thousand,
12 1 million, 10 million to a hundred million?

13 A. Yes, I do. It's on a log scale.

14 Q. Is it normal in the field of statistics to
15 present a Y axis that has such a large
16 variance in increments on the Y axis?

17 A. It is normal.

18 Q. It is. If the scale of the Y axis had been
19 reduced to something like 1 to 10,000, would
20 the difference between no air, ambient air
21 and warm air appear to be more significant
22 than it does on the graph as it is?

23 A. Yes, they would -- it would appear to be --
24 oh, wait, it -- oh, between no air, ambient
25 air and warm air?

1 NACHTSHEIM

2 Q. Uh-huh.

3 A. It would look like a larger difference.

4 Q. And if you look at the graph beneath that and
5 we compare no air, ambient air and warm air,
6 what is the value of the particle
7 concentration at no air?

8 A. One thousand.

9 Q. What is the particle concentration for warm
10 air?

11 A. For warm air it's a little hard to tell,
12 because of the log scale, but it's -- I don't
13 know, it's probably -- probably -- it might
14 be 5 or 6,000, I'm not sure.

15 Q. So it appears that there is about a five
16 times increase in particle concentration
17 compared to no air?

18 A. Correct.

19 Q. If the underlying raw data of this study
20 showed there to be a p-value of 0.06 with
21 respect to the difference in particle
22 concentration between the use of no air and
23 warm air from the Bair Hugger, would you
24 consider that to show statistical
25 significance?

1 NACHTSHEIM

2 A. 0.06, we tend to call that marginal
3 significance.

4 Q. If you had generated a p-value of 0.06 in one
5 of your own studies that you were a coauthor
6 of, would you have noted in the paper
7 addressing that data that there was a nearly
8 statistical significant result?

9 MS. GARCIA: Object to the form of
10 the question.

11 THE WITNESS: I very well might.
12 And, particularly, if it went in the
13 direction of, say, theory or there was some
14 expectation, but anyway, it's common to
15 say -- say marginal.

16 MR. SACCHET: I have hours of more
17 questioning, but for the sake of being
18 gracious, I will allot the last remaining
19 minutes to you to ask whatever you need to
20 ask.

21 MS. GARCIA: Thank you.

22
23 EXAMINATION

24 BY MS. GARCIA:

25 Q. I just wanted to clarify a couple of things

1 NACHTSHEIM

2 with respect to Exhibit 27, please. This is
3 the one page that bears the Albrecht number
4 on the bottom.

5 I just wanted to be sure I
6 understand, do you have any knowledge about
7 this analysis or what it represents beyond
8 simply looking at the piece of paper?

9 A. No.

10 Q. Do you know what antibiotic protocol 1 or
11 antibiotic protocol 2 is?

12 A. I think those -- those refer to --

13 Q. Do you know?

14 A. It's what we talked about in the paper.

15 Q. Well, we have -- I understand that there was
16 a connection made to what's in the paper, but
17 do you know for sure which is antibiotic
18 protocol 1 or 2 or whether either of it
19 relates to what's in the paper, do you
20 actually know that?

21 A. I -- I suppose I -- well, I assumed that it
22 had to do with what we read in the paper
23 about the change in protocols.

24 Q. Do you have any information about what it
25 actually represents?

1 NACHTSHEIM

2 A. No, there's nothing here.

3 Q. And do you know when in time this analysis
4 was conducted?

5 A. I do not.

6 Q. And do you know for sure that the data set on
7 which it was conducted is the same data set
8 as the McGovern paper?

9 A. I do not.

10 Q. And you were asked a series of questions
11 about antibiotics and anti prophylaxis.
12 Exhibit 28 is a paper that was apparently --
13 that was -- is marked as having been produced
14 from your files. Do you know any of the
15 authors on this paper?

16 A. Let's see, I don't believe I do. I mean, I
17 know who Mike Reed is.

18 Q. Okay.

19 A. But I don't know any of the other authors.

20 Q. Do you have any information about how well
21 this study was designed or conducted?

22 A. No, and that's why I think I answered some of
23 the questions saying assuming this was a
24 well-done study then --

25 Q. You also said assuming it was generalizable,

1 NACHTSHEIM

2 you might be able to make some conclusion
3 based on that. Do you have any information
4 about whether this study is generalizable?

5 A. I have none at this moment.

6 Q. Okay. And do you have any information about
7 whether the findings in this study would be
8 relevant to the analysis or investigation
9 that you made in the McGovern study? Not
10 that you made, that was made in the McGovern
11 study.

12 A. That was made in the McGovern study. Well,
13 it seems relevant since they were looking at
14 infections.

15 Q. Do you have any expertise in medicine and the
16 treatment of infection?

17 A. No.

18 Q. Do you have any infectious disease expertise?

19 A. No.

20 Q. Do you know enough about this paper to give
21 any type of opinion about whether what it
22 represents is in fact relevant to what was
23 done at the Northumbria Health System?

24 A. Yeah, so my opinions were under the
25 assumptions that this was -- these were the

1 NACHTSHEIM

2 same -- these were the same drugs and we were
3 counting the same kinds of infections.

4 Q. Do you know that to be the case?

5 A. I don't know that to be the case.

6 Q. And even if there were findings about the
7 effect of a drug in one particular study,
8 perhaps Exhibit 28, would that necessarily
9 translate to the content -- the context of
10 Northumbria?

11 A. Not necessarily.

12 Q. And the other confounding factors,
13 potentially founding -- confounding factors
14 that we discussed, still exist with respect
15 to the McGovern paper, correct?

16 A. The others, yes.

17 Q. And would knowledge about how those changes
18 might relate to either the data presented in
19 exhibits -- in Exhibit 27, or any antibiotic
20 drug effect presented in Exhibit 28, be
21 important?

22 A. Now, you're -- and you're talking about the
23 other --

24 Q. Yes.

25 A. -- confounding factors, not -- other

1 NACHTSHEIM

2 potential factors that we may or may not know
3 about?

4 Q. Yes. Those would still be important?

5 A. Those could still be important.

6 Q. Okay.

7 MS. GARCIA: That's all I have.

8 Thank you.

9 THE VIDEOGRAPHER: We're going off
10 the record at 5:45 p.m.

11 (Whereupon, a brief discussion
12 was held.)

13 THE WITNESS: This is my updated
14 CV.

15 MS. GARCIA: Yes, that will be the
16 record copy.

17 (Whereupon, Exhibit 30 was
18 marked for identification.)

19 (Whereupon, the foregoing
20 deposition concluded at 5:48 p.m.)

TSG Reporting - Worldwide 877-702-9580

1
2
3 I, Christopher Nachtsheim, have read this
4 deposition transcript and acknowledge
5 herein its accuracy except as noted:
6

7
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12
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25

Witness Signature

1 STATE OF MINNESOTA)
) ss
2 COUNTY OF ANOKA)
3

4 Be it known that I took the foregoing
deposition of Christopher Nachtsheim, on
November 29th, 2016, in Minneapolis, Minnesota;
5

6 That I was then and there a notary public
in and for the County of Anoka, State of Minnesota,
and that by virtue thereof, I was duly authorized
7 to administer an oath;

8 That the witness was by me first duly
sworn to testify to the truth, the whole truth and
9 nothing but the truth relative to said cause;

10 That the foregoing transcript is a true
and correct transcript of my stenographic notes in
11 said matter;

12 That the witness reserved the right to
read and sign the transcript;
13

14 That I am not related to any of the
parties hereto, nor interested in the outcome of
the action;
15

16 WITNESS MY HAND AND SEAL this 9th day of
December, 2016.
17
18

19 Amy L. Larson, RPR
My Commission Expires 1/31/2020
20
21
22
23
24
25